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# **An Enquiry into Biosafety Regulations Implementation in Kenya: Perspectives and Roles of Scientists**

Thesis submitted in partial fulfilment of the requirements for the  
Research Degree of Doctor of Philosophy

Development Policy and Practice  
Faculty of Mathematics, Computing and Technology  
The Open University  
Milton Keynes  
United Kingdom

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## DEDICATION

This thesis is dedicated to the glory of the living God who has seen me through from the beginning to the end, according to His promise in Zechariah 4:6-7 which reads:

*“You will succeed, not by military might or by your own strength, but by my spirit.  
Obstacles as great as mountains will disappear before you”*

# Abstract

This thesis explores the perspectives and related behavioural shifts of the heterogeneous Kenyan scientific community in the development and subsequent implementation of biosafety regulations. Kenya's biotechnology innovation system has been driven largely by the contradictory framing of biotechnology as a scientific tool for innovation and international competitiveness on the one hand, and as a technology that has adverse effects on the environment on the other. A transition towards an integrated regulatory system over the last one and half decades had entailed unprecedented institutional configurations and changes in behavioural patterns of the scientific community.

To analyse the role of the scientific community in shaping the regulatory process and instruments in the evolving biotechnology innovation system, the thesis draws on interviews, documentary analysis and observation data collected from a wide range of scientist and non scientist actors. It finds that, as scientists adapt to institutional changes necessitated by the biotechnology innovation transition, they have been reconstituting themselves consciously and unconsciously around different linear and non linear modes of knowledge production. In the process, learning has occurred, knowledge has been produced and diffused impacting on both technological innovation and emergence of a regulatory regime. The latter is however bounded up in the former. The thesis further finds that the capacity to influence the regulatory process and instruments was spurred not only by the individualised scientific expertise, but also by the relationships and coalitions built around the different regulatory phases. Knowledge produced in this regulatory context challenges the application of knowledge theories in the light of its potential to influence scientific practice and regulatory policy instruments. From lessons and insights drawn from theories of knowledge, the emerging policies and practices are skewed towards a narrow, linear form of technical and scientific expertise, thus ignoring many underpinning factors that are important for emergence of socially desirable processes and policies. The study recommends reconceptualisation of both scientific practice and policy-making in reflexive and systemic ways that encourage incremental learning.



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And to my husband Gitau, I can only say that you provided more than what my heart can express on paper. Stepping in to play the role of a mother in my absence is something I will for ever be grateful. My two lovely angels Wairimu and Wanjiru who endured my absence but nevertheless understood and respected my desires, is something I will always cherish. On a personal level, I thank God for bringing Maggie Njambi my way who has taken good care of my family as if her own and Kihui's family for moral support. May God bless you all.

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# Abbreviations

AATF	African Agricultural Technology Foundation
ABSF	African Biotechnology Stakeholders Forum
ABSP	Agricultural Biotechnology Support Programme
ACTS	African Centre for Technology Studies
ASCU	Agricultural Sector Coordinating Unit
ATPS	African Technology Policy Studies Network
BioAWARE	National Biotechnology Awareness Strategy
BIOEARN	Eastern African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
BTA	Biotechnology Trust Africa, Kenya
CBD	Convention on Biological Diversity
CFTs	Confined Field Trial/s
CGIAR	Consultative Group on International Agricultural Research
CIN	Consumer Information Network
Codex	Codex Alimentarius Commission of FAO
CPB	Cartagena Protocol on Biosafety
CIMMYT	International Maize and Wheat Improvement Centre
DGIS	Directorate General International Cooperation (of the Netherlands)
DPH	Department of Public Health
DVS	Department of Veterinary Services
EAC	East African Community
ESRC	Economic and Social Research Council
FAO	Food Agriculture Organisation
G(L)MOs	Genetically (Living) Modified Organisms
GDP	Growth Domestic Product
GE	Genetic Engineering
GEF	Global Environment Facility
IBC/s	Institutional Biosafety Committee(s)
ICIPE	International Centre of Insect Physiology and Ecology
ICTSD	International Centre for Trade and Sustainable Development
IFPRI	International Food Policy Research Institute
ILRI	International Livestock Research Institute
INNOGEN	Centre for Social and Economic Research on Innovation in Genomics
IPPC	International Plant Protection Convention
IRI	International Research Institute
IRMA	Insect Resistant Maize for Africa
ISAAA	International Service for Acquisition of Agri-biotechnology Applications
ISNAR	International Service for National Agricultural Research
ISPM	International Standards for Phytosanitary Measures
KABP	Kenya Agricultural Biotechnology Platform

KARI	Kenya Agricultural Research Institute
KBC	Kenya Biosafety Coalition/Kenya Biotechnology Coalition
KBioC	Kenya Biodiversity Coalition
KEBS	Kenya Bureau of Standards
KEGCO	Kenya GMO Concern Coalition
KEMRI	Kenya Medical Research Institute
KENFAP	Kenya Federation of Agricultural Producers
KEPHIS	Kenya Plant Health Inspectorate Service
KIPI	Kenya Industrial Property Institute
KIRDI	Kenya Industrial Research Development Institute
KSTCIE	Kenya Standing Technical Committee for Imports and Exports
MOA	Ministry of Agriculture
MOHE,S&T	Ministry of Higher Education, Science & Technology
MOPH&S	Ministry of Public Health & Sanitation
NACBAA	National Advisory Committee on Biotechnology Advances and their Applications
NBA/NBC	National Biosafety Authority/ National Biosafety Committee
NCST	National Council for Science and Technology
NEMA	National Environmental Management Authority
NEPAD	New Partnership for Africa's Development
NGOs	Non-Governmental/Non State Organisations
OAU	Organization of African Unity (now African Union)
OECD	Organization for Economic Cooperation and Development
OFAB	Open Forum on Agricultural Biotechnology in Africa
PBS	Programme for Biosafety Systems
PCPB	Pest Control Products Board
PRI	Public Research Institute
RA	Risk Assessment
rDNA	recombinant DeoxyriboNucleic Acid
SRA	Strategy for Revitalisation of Agriculture
STI	Science, Technology and Innovation
STS	Science and Technology Studies
UNEP	United Nations Environmental Programme
USAID	United States Agency for International Development
WTO-SPS	World Trade Organisation – Sanitary and Phytosanitary (agreement)

## 1 Introduction

It has taken Kenya about one and half decades to develop and implement a functional biosafety system in spite of all the available technical capacity and promises from new biotechnologies. This scenario presents an excellent opportunity to investigate the role of the scientific community in the delayed biosafety regulatory process.

Many policy reports seem to support the view that modern biotechnology or genetic engineering technology (GE)<sup>1</sup> will have a positive impact on economic development as it has the potential of improving agricultural production, particularly in developing countries (cf RoK, 2006a in Kenyan context; Juma and Serageldin, 2007 in regional context). Efforts towards this goal are hampered by controversies related to safety of its application. As a result it is highly regulated through biosafety regulations<sup>2</sup> which are instruments for meeting an acceptable level of governance. At the global level, this regulation is provided through the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol, 2000).

Development of requisite biosafety regulations involves intensive input of expertise because of the technical nature of biosafety. Consequently, the scientific community has been called upon to resolve these technical and high profile controversies, thus getting entangled in the process as experts in biosafety policy (Scoones, 2002) and policy targets in biotechnology development (Chataway *et al.*, 2006).

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<sup>1</sup>The application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (Cartagena Protocol, 2000). It is used interchangeably with genetic modification (GM).

<sup>2</sup>Biosafety is the avoidance of risk to human health and safety, and the conservation of the environment as a result of the use of products of GE [Biosafety Act, 2009 (RoK, 2009)].



This thesis therefore examines how biological scientists in Kenya perceive the biosafety regulations related to modern biotechnology and how these perceptions shape the implementation of regulations. The study in particular explores how these perceptions are constructed around the regulatory process in relation to GE technology and the perceptions related to scientific and regulatory roles and behaviour. Further, the study aims to understand how the perceptions around regulations and regulatory practice shaped the regulatory instruments and what the implications this might have for the broader biotechnology innovation system in terms of knowledge use for economic development.

The purpose of this chapter is to demonstrate the importance of researching the implementation of regulations, and why the scientific community is a key target group to focus on. It presents the background to the study, its aim, research questions, the study approach, the findings and some key definitions.

## **1.1 Background**

### ***1.1.1 Kenya's biotechnology innovation at a glance***

Kenya's Science and Technology (S & T) policies emphasize the importance of agriculture in economic development. The recently launched Kenya Vision 2030 (RoK, 2007b) and the Science and Technology Innovation Policy and Strategy (RoK, 2007a) attest to this. However, in the agricultural sector, the post green-revolution era has been characterised by poor performance due to various biotic and abiotic production constraints (RoK, 2005a; De Groote *et al.*, 2005 in their reference to maize). Advanced technological tools are poised to address some of these constraints like pests, diseases, weeds control and drought (Kelemu *et al.*, 2003). Modern biotechnology has been earmarked as one of the tools to address these challenges [(Strategy for Revitalisation of Agriculture (SRA) (RoK, 2005a)].

As will be shown in Chapter two, endeavours to introduce GE technology started in the early 1990's, with a hope of producing products such as transgenic sweet potato, towards addressing food security challenges. Developing a GE product takes a long time particularly at the laboratory stage because GE involves gene manipulation. However, in Kenya like in many developing countries, scientists did not have to re-invent the wheel as most of the activities being undertaken have been provided already transformed in developed laboratories in technologically advanced countries like USA (see AATF at [www.aatf-africa.org](http://www.aatf-africa.org)). This being the case, deploying the technology for economic competitiveness and use by farmers was expected to take a shorter duration. This has not been the case and almost 20 years down the line, there are no commercialised products available.

Many factors are attributed to this, one being the regulatory requirements imposed on the technology world-over that originate from the fear and uncertainties about claimed benefits and risks (Bananuka, 2007; Paarlberg, 2001; Nang'ayo, 2007). Regulation therefore is hampered by competing value-laden perceptions, aggravating technology deployment. Consequently, governments have been faced with a difficult task of balancing the perceived beneficial claims and perceived risks as citizens adopt different views. The biosafety regulation is therefore intended to serve a dual purpose - to address these ambivalences as well as facilitate the deployment of biotechnology for economic use (RoK, 1998; RoK, 2006a). This is where Kenya finds herself and the process of establishing a sustainable biosafety regulatory system has been a challenging task. Further to this, the political economy of Kenya's biotechnology is such that Kenyan scientists depend on foreign institutions for research support partly because of the reduced government funding for public research (Beintema *et al.*, 2003; Odame *et al.*, 2003).

### ***1.1.2 Role of the heterogeneous scientific community in this study***

The scientific community is one group of Kenyan citizens that has been widely mentioned in connection with the regulatory process (Harsh, 2008; Sander, 2007). The community considered in this study comprises of mainly biological and a few non biological scientists, but heterogeneous in various respects; profession, organisation (employer) and discipline. Moreover, they are spread out in different sectors that deal with biosafety regulations as policy makers, regulators, practitioners, industry, Non Governmental Organisations (NGOs) in civil society and pro-biotechnology organisations, and academic institutions among others. To simplify the diversity and enhance analysis of perceptions, they are categorised into three non homogeneous groups as follows:

- GE Practitioners (GP) are those scientists who are (or have previously) engaged in contained and confined research involving genetically modified crops and vaccines. Some claimed to be passionate about GE work.
- Policy Scientists (PS) are either senior government officials and biological scientists in the National Biosafety Committee (NBC) and/or Institutional Biosafety Committees (IBCs) and regulatory institutions. The senior government officers are (or have been heads of government institutions or ministries). The scientists in the NBC and IBCs are generally from public academic institutions, regulatory agencies and one international research organisation. Some of them are affiliated to other professionally related institutions. Participants in this group identify with GE research in one way or another.
- Non State Scientists (NSS) belong to non-governmental organisations (NGOs) that have a stake in biotechnology activities. They support biotechnology activities in various ways like funding or awareness creation. They are backed up by their biological science background.

Besides the scientists, another category of non biological scientists was considered in this study. They are spread out in civil society, lawyers, journalists, biotechnology industry and funding organisations, and include social scientists.

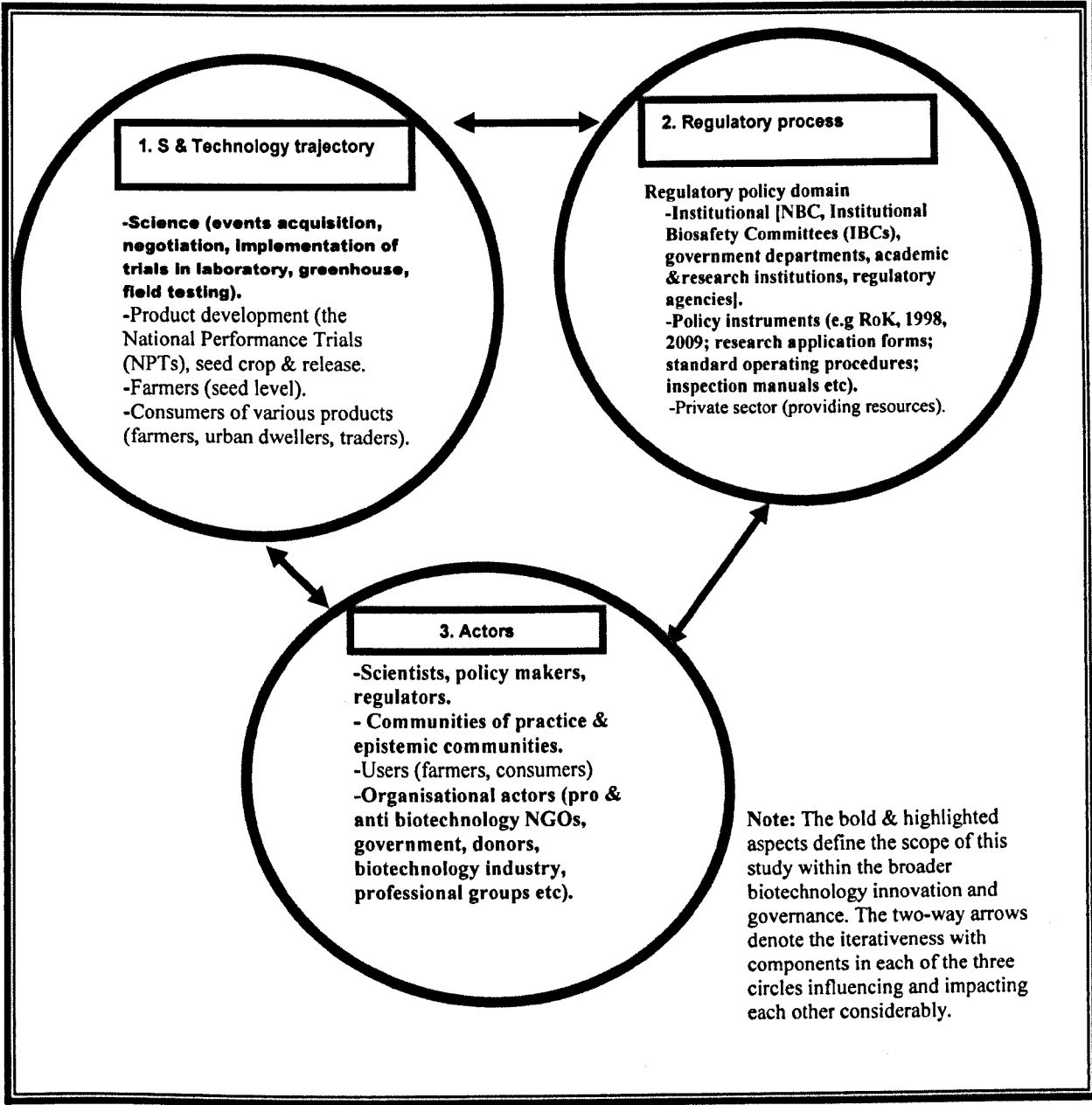
The Kenyan scientific community has been associated with implementation of biosafety regulations in three significant ways: Firstly as individuals or within knowledge-based groups, they comprise of proactive actors in the development of a purportedly effective biosafety system (Harsh, 2005; Sander, 2007; Odame *et al.*, 2003 and Appendix 9). Secondly, products of GE technology (in form of research) have been at confinement stage and have not been exposed to the public. This may imply that most of what is being debated has been at the hands of the scientific community. Thirdly, the group had expressed concerns regarding regulations implementation in the light of their dual role in implementation as policy targets and policy developers. This is in relation to decision-making processes pertaining to research trials and policies on the one hand; and executing, managing, enforcing and monitoring the trials on the other (pilot study carried out between Dec 2006 and Jan 2007; Paarlberg, 2001; Mugo *et al.*, 2005).

This puts scientists in an awkward and compromising position, that of developing regulations and that of enforcing them. Their contribution to the biotechnology development is undoubtedly key to the eventual deployment of the technology for economic gain. In addition, their role in the construction of requisite regulatory instruments cannot be underestimated because they are interested parties.

### ***1.1.3 The technological, institutional and individual actor dynamics***

Fig (1) below illustrates the issues raised in this section highlighting how the regulatory process has been bound up in the broader biotechnology innovation system. It also defines the scope of the study by situating the scientific community within the

multiplicity of actors involved in the biotechnology innovation process. The framework illustrates technological, institutional, individual actors and linkages between them that interplay significantly as components to influence the multifaceted dynamics in the overall innovation process, including regulatory process.



**Figure 1:** A non-linear, iterative illustration of a complex interrelationship between components in governance of biotechnology in Kenya.

**1.2 Research problem**

This study set out to achieve a number of objectives. Firstly, to look at the factors that impact upon the way biosafety regulations are implemented in practice. Secondly, to

situate the role of different actors and in particular those in the biotechnology science and biosafety arena, in policymaking and the systemic issues that determine the way these roles are articulated. Thirdly, illuminate actors framing of issues around the first two considerations (implementation of regulations and role of scientists in regulatory policy-making) and the motivations behind the emerging discourses. Fourthly, by weaving these discourses together, establish how the scientific community impact upon or influence regulatory instruments in terms of context and content as this would have implications for broader innovation policies and eventual biotechnology deployment.

### ***1.2.1 Rationale and research questions***

Development of an effective regulatory system for management of biotechnology innovation has been an important institutional innovation. This has been debated under the broader decision-making processes linked to governance of the new life sciences (cf Tait *et al.*, 2009a). Actors have had to adjust to accommodate the unprecedented and requisite institutional and organizational revolutions that have accompanied these new innovations. Despite this dynamism, the knowledge being produced by both the institutions and the individual social actors in the process of adaptation has not been given enough consideration. In particular, the knowledge being produced in the regulatory process seems to collide with other linear and non linear forms of technological knowledge impacting upon the behaviour of actors. This thesis argues that articulation of regulatory knowledge in policy-making may open up a new way of studying scientific practice and knowledge production dynamics. Arguably, literature around knowledge production dynamics involving experts and policy-making (Gibbons *et al.*, 1994; Nowotny *et al.*, 2001; Haas, 1992, 2004) has not articulated the regulatory context under which knowledge in the new life sciences is generated. This knowledge tends to be political and value laden as asserted by Jasanoff (1990) and Murphy and Chataway (2005).

The institutional changes that characterise new knowledge production terrain as described by proponents of Mode 2 tend to underplay the corresponding adaptation that social actors have to undergo in the process (Gibbons *et al.*, 1994).<sup>3</sup> This thesis argues that this adaptation is embedded in existing and evolving cultural practices<sup>4</sup> that influence the nature and form of knowledge produced, and how it is used. Drawing insights from two strands of literature, sociology of science scholarship on the one hand and innovation systems on the other, provides a new framework for investigating regulatory processes in practice and the role of actors. This consequently informs the context for governance of the new life sciences like agricultural biotechnology based on empirical evidence.

These arguments rest on the understanding that the actors involved in policy formulation or implementation need to be aware of the different types of knowledge produced for the purposes of policy-making in areas that are knowledge intensive like biotechnology. Scientific knowledge is only one type of knowledge and can originate from different sources (e.g. individual or institutional/organisational). More important is the way these forms of knowledge are utilised for policy-making to legitimise the process on the part of the policy makers, those being regulated like researchers and the broader public. In the Kenyan context, as the scientific community engages with biotechnology institutions which they are part of (research, non-research, regulatory instruments etc), knowledge is produced and diffused in the process, perceptions are constructed and coalitions emerge. The technological and political nature of the Kenyan regulatory policy process also has an impact. All these factors put together impact on

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<sup>3</sup> Mode 2 describes the changing nature of knowledge production in contemporary research but from the broader institutional context (Gibbons *et al.*, 1994).

<sup>4</sup> Culture with respect to development refers to creative abilities of man expressed through re-organisation of social existence via a set of institutions, regulations and values but may vary based on purpose and individual (Mabawonku, 2003:118). Mabawonku further notes that a particular group's cultural practice can be conceptualised in terms of incidence or preference of behaviours or the actions of this group. See also section 1.5 of this chapter for a detailed definition of the term culture as applied in this thesis.

the regulatory process and instruments, and the broader innovation policies and implementation.

In order to empirically explore the above arguments, research questions were designed to elicit views from a heterogeneous group of the scientific community (Appendix 1) regarding their experiences in the implementation of biosafety regulations. These questions were:

1. What are the perspectives of scientists on implementation of biosafety regulations and why might they be holding these views?
2. Have the practices of scientists related to implementation of biosafety regulations shaped the evolution of the regulatory process, and if so how?
3. What is the implication of the scientific practice on the biotechnology innovation policies and knowledge use?

### ***1.2.2 Motivation of the study***

The focus of this study as explored in this section is important for biotechnology governance and its impact on deployment of biotechnology products for economic usefulness in Kenya. The literature briefly analysed below and further in Chapter two (see section 2.5) suggests a compelling argument that biotechnology and biosafety systems have co-evolved, and that multiple actors have been involved.

A study by Odame *et al.* (2002, 2003) yielded general statements on the role of the scientists in the policy-making process and the possible outcome. Other studies have presented positive statements pointing towards engagement of scientists in the biotechnology regulatory policy process (Sander, 2007; Harsh, 2005, 2008). Harsh and Sander in particular seem to have come closer to the phenomenon under consideration in this thesis; the governance of modern biotechnology. Their work focused on



perceptions and regulatory practice involving scientists in various ways but within their broader institutional settings (e.g. NGOs and research institutions). An institutional approach seemed to be yielding useful data but it was masking the role of scientists in biotechnology governance either as individual entities or within institutionalised settings.

This study specifically looks at scientists as social actors bound up in their institutional settings (as opposed to the institutional focus applied by previous scholars). Taking this path has various implications. It made me focus on the role of scientific community as a social institution in the regulatory policy-making process and meant that I did not focus directly on controversies relating to biotechnology. This approach does not however take for granted the role of the broader public in policy-making. Instead, I focused on a better understanding of role of the scientific community in public policy-making and the implications of their practices for the wider public policy. Previous studies, perhaps because of the technological and broader institutional approach, tended to mask specific innovations (like policy or regulatory) which are important for the overall functioning of the biotechnology innovation process in the risk governance context.

Analysis of the empirical data focuses on the research stage since at the time of field work, biotechnology research had not gone beyond field trials. Thus, it is more oriented towards particular innovations (e.g. regulations) and the context under which they have evolved. The concentration on modern biotechnology in agricultural innovation presents a good opportunity to investigate the dynamics involved in policy and institutional innovations, particularly in the context of the controversies associated with governance of the new life sciences in Africa.

Another justification for this study relates to my professional background (see Chapter four, section 4.2). During my 8 years working as a regulator and interacting with biological scientists (myself being one), I observed technical and policy related tensions that can occur between the scientists interested in GE technology on the one hand and scientists in the policy and regulatory arena on the other. This drove me into asking hypothetical questions related to this technology on the one hand and regulations on the other. For instance, I asked myself what is so special about GE technology and what made practitioners frustrated during implementation of regulations? Reflecting on these probing issues, I could see a disconnect between different categories of scientists (those with policy orientation and those involved in practice) and a gap between regulatory instruments and what they are meant to achieve (facilitation and regulation according to RoK, 1998). This observation seemed to suggest that a lot of the tension around regulation implementation was to do with perceptions and consequent actions (practice). This again points towards the importance of focussing on the scientific community which has already been identified in the preceding sections as active players in biotechnology and biosafety arena.

### **1.3 Research methodology**

Chapter four presents in detail how the above research questions were tackled. Kenya was considered as a particular study area where the above-mentioned phenomenon could be examined. There were many advantages for choosing Kenya as justified in Chapter two and further detailed in Chapter four. As the research questions indicate, the study has both components of perceptions of regulations and perceptions of practice (in the process of implementing the regulations). The methodology employed in this study therefore focussed on eliciting these different perspectives. The complex factors that confront the biosafety regulation arena as described in the background section were kept

in mind during the entire research process. An interdisciplinary approach was adopted that incorporated both empirical and theoretical research approaches.

To generate rich empirical data, a qualitative approach was adopted that resulted in use of engaging methods - semi-structured interviews complemented by observations and documentary research as sources of data and/or way of corroborating the accounts of the interviewees. This yielded detailed understanding around the dynamics that shape the process of policy-making in biotechnology innovation. The non-scientist interviewees served a dual purpose in this research: firstly, they corroborated certain specific issues related to views of scientists and regulatory practices and secondly, as source of data on certain aspects of this research such as nature of regulations and regulatory process. Validity was checked in various ways through different sources of data and different methods.

Data generated via these methods were coded and analysed deductively and inductively. As this process was data led, it enhanced further validation and led to the emergence of interesting themes that form the substance of the empirical chapters. Since the relationship between perceptions and regulatory practice is key in this study, cognitive mapping was used as a tool to display visually the thoughts of scientists about regulations and related actions taken towards articulating these thoughts (influence). This is important because visual maps are amenable to analysis for policy actions and recommendations (Eden, 2004). This tool enhanced tackling of the third research question which is policy-oriented.

Several conceptual and theoretical approaches were considered to complete the investigation process by grounding the empirical data in theoretically sound concepts.

## 1.4 Summary of findings and implications

Findings emanating from analysis of the rich empirical data generated from this study suggest the following:

- The heterogeneous scientific community has contrasting views of regulations and regulatory process built around the prospects of biotechnology in addressing food production constraints on the one hand, and risk perception, on the other. Unlike other related studies, this study has empirically exposed complex technical and social factors (capacities, values, beliefs, interests, globalisation and reduced funding of public research among others) that collectively shaped the evolving perceptions of scientists of regulatory process and practice.
- Different values exhibited by the scientific community reflected cultures of different social knowledge groups and coalitions that they belong to (academic disciplines, professional and policy groups). This scenario presents a different way of interrogating knowledge use, departing from the way it has been researched by various scholars (Gibbons *et al.*, 1994; Nowotny *et al.*, 2001; Haas, 2004). It has also opened up a new way of looking at knowledge flow and relationships building, augmenting the interactions and cumulative learning emphasised in innovation systems and policy networks literature.
- The scientific community engages in various ways in regulatory and scientific activities which is consistent with Mode 2 integrated practice. The context under which these activities are articulated has informed better understanding of specific concepts that speak about knowledge and knowledge production dynamics. For instance, knowledge production and use in a regulatory context is complex and value laden which tends to challenge application of Mode 2 principles.
- The Mode 2 research environment impacts scientific behaviour which ultimately affect how knowledge is eventually used in regulatory decision-making processes

based on the underpinning complex context. This calls for rethinking of role of knowledge and scientific practice in the regulation of biotechnology contributing conceptually to the growing scholarship around governance of the new life sciences.

- The institutional shortcomings that were revealed in the process of regulations implementation suggest a need for policy makers to reconceptualise governance approaches to regulation of biotechnology research towards regulatory models that are pro-innovation.

## 1.5 Definitions

A number of concepts which have been used extensively in the thesis are explained briefly:

***Modern biotechnology/ genetic engineering (GE)***: manipulation of living organisms to produce goods and services useful to human also referred to as genetic engineering (GE). It is distinguished from traditional (or conventional) in that it is a modern or transgenic approach that develops products (such as seed varieties) through insertion of genetic material from different species into a host plant. It can also be defined as the application of in-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles (Cartagena Protocol, 2000). The products derived using these techniques are commonly referred to as Genetically Modified Organisms (GMOs).

***Biosafety***: the avoidance of risk to human health and safety, and the conservation of the environment as a result of the use of products of GE [Biosafety Act, 2009 (RoK, 2009)]. In broader terms, it encompasses the regulatory mechanisms that the government has put in place for the governance of GE activities in order to balance the views between perceived technological benefits and safety (Cartagena Protocol, 2000).

**Regulation:** The term has many meanings such as “assignment of authority to a decision-making body” (Dworkin, 1996 cited in Andanda, 2006:1362). In the case of biosafety which is the focus of this study, the definition by Braithwaite *et al.* (2007), is more appropriate as it argues that governments and governance are about providing, distributing and regulating. It encompasses both those regulating and those being regulated, bringing to the fore important components of regulatory practice:

*“Regulation can be conceived as that large subset of governance that is about steering the flow of events and behaviour, as opposed to providing and distributing.”* (Braithwaite *et al.*, 2007:3)

**Regulations implementation:** This concept is used interchangeably with **regulatory process**. According to UNEP-GEF, biosafety implementation is encapsulated in the term **regulatory regime** that “comprises all those legal instruments (laws, acts, regulations, decrees, orders, guidelines etc) that are relevant to the regulation of GMOs activities including the institutional arrangements for implementing those regulations” (UNEP-GEF, 2004). The concept is used in this thesis to denote two main aspects: firstly, activities related to risk assessment (RA), risk management (RM) and risk communication (RC) in execution of GE trials and secondly, the formulation of regulatory instruments. Based on these two aspects, **regulatory practice** refers to the role played by scientists in the implementation of regulations, including the institutional context under which they articulate this role.

**Culture:** From innovation systems perspective, culture is conceptualised as institutions or habits and customs that define patterns of behaviour and shape human interactions (Coriat and Weinstein, 2002:279). Huzair (2008:219) referring to the scientific community and biotechnology research further argues that culture [and the related cultural practices] underpins networks and learning associated with this community. Ultimately, this culture gives “this community distinct characteristics and behaviours which evolve over time to cope with the changing context” (*Ibid*). Cultural practice in

this research in Kenya therefore refers to the behaviour of the scientific community in the implementation of biosafety regulations in the context described in Chapter two.

**Actors:** Based on Ayele's (2007a) description, actors in biotechnology and biosafety arena encompass those parties concerned with, and affected by decision-making processes. They share values and interests, and have the power to thwart a decision through various means like formation of coalitions. The term is used in this thesis to refer to individual social actors like scientists and the affiliated organisations/institutions. These organisations (as demonstrated in Chapter two) are nodes of knowledge production in the context of biotechnology innovation system and regulatory process. The scientific actors who participated in this study were selected from these diverse knowledge nodes.

**Scientific community:** is a subset of actors used in this research to refer to scientists in research, academia, NGOs and policy arena. This group is engaged in biotechnology activities or debate but with background training in mainly biological sciences (Appendix 1). A *scientist* is considered to have various scientific and regulatory roles in biosafety regulations implementation process - reviewer of GMOs applications, risk assessor, risk manager in an effort to comply with biosafety standards and inspection or monitoring manuals and protocols, researcher in his respective professions and provider of advisory service in biosafety committees for policy decisions (Jasanoff, 1987, 1990; Newell, 2002; Maclean *et al.*, 2002). He also plays an expert role in the science policy deliberations like in formulation of environmental policies or factual public education (Haas, 1992, 2004; Weingart, 1999; Sense about Science report, 2009).

**Boundary organizations:** These are sites of simultaneous production of knowledge and social order facilitating collaboration between scientists and non scientists (Guston, 2001). They create a combined scientific and social order through the generation of

*boundary objects* (e.g. regulations) and standardised packages. In the Kenyan context, the National Biosafety Committee (NBC) and regulatory agencies can be considered to be boundary organisations and the biosafety bill/Act (or biosafety regulations) may be perceived to be boundary objects.

## **1.6 Overview of the thesis structure**

The rest of this thesis is structured as follows: **Chapter two** presents a detailed description of the Kenyan context in relation to modern biotechnology and regulatory instruments evolution since 1990's when biotechnology programme was initiated in Kenya. Emphasis is given to the role of scientists who are the focus of this thesis and their interaction or involvement in the implementation of biosafety regulations and regulatory policies. This brings to the fore the context within which they implement the biosafety regulations and the contextual factors that interplay in the construction of a purportedly effective biosafety system, for the governance of modern biotechnology. **Chapter three** reviews relevant literature related to knowledge production and use, biotechnology governance with a focus on biosafety regulation and the role of scientific actors in controversial policymaking. Key theoretical concepts and approaches are reviewed to situate the study within the broader science and technology studies and policy-making. In **Chapter four** methodological approaches and instruments employed to undertake this study are discussed. These include both the empirical and theoretical approaches that guided the data generation, analysis and interpretation. In **Chapter five** and **six** empirical data generated is presented. In **Chapter seven** there is further analysis and discussion of the data, weaving together the empirical data and the theoretical concepts. **Chapter eight** summarises and concludes the thesis.



## 2 The Co-Evolution of Biotechnology and Biosafety Institutions in Kenya

### 2.1 Introduction

Building on some of the studies on biotechnology governance in Kenya (discussed further on), this chapter calls attention to the importance of the various aspects of technological, regulatory and social local contexts in which the scientific community, related actors (e.g. organisations) and regulatory process are embedded. It seeks to provide the regulatory context for the subsequent chapters as well as situate the scientific community as actors engaged in biotechnology research and development (R & D) for the last two decades within the process of regulation implementation. By doing this, the chapter exposes the motivations and opportunities for the scientists in their engagement with biosafety regulatory process and formulation of regulatory instruments, and the institutional challenges and strengths related to modern biotechnology governance. This prepares the requisite background needed to respond to the research questions stated in Chapter one.

The content of this chapter is drawn from empirical data gathered from the interviews, complemented with secondary data (such as literature and relevant Kenyan documents) and observation data. It sets the scene for the more data oriented empirical chapters that follow. In what follows, the next section provides the current status of science and technology policies situation in Kenya, followed by a discussion of biotechnology development and biosafety regulation evolution both in general terms and in the context of the role of the involved multiple actors. The chapter concludes with a critical analysis of the evolutionary trend of the different phases of the regulatory system trajectory and a brief review of literature around governance of biotechnology in Kenya.

## 2.2 Science and Technology (S&T) policies

Agriculture is the cornerstone of Kenyan economic development although performance has often been poor due to various production constraints (RoK, 2005c; RoK, 2005a). Biotechnology is seen as one way through which the production constraints can be addressed (RoK, 2005a; RoK, 2006a). Until recently, none of the S & T policies had incorporated biotechnology. However, there have been significant milestones towards addressing the policy vacuum reported widely by many scholars with regard to biotechnology research and development (R & D) as well as biotechnology innovation (Odame *et al.*, 2002; Harsh, 2005, 2008).

A biotechnology policy was approved in 2006 (RoK, 2006a), while the Biosafety Act was approved in 2009 (RoK, 2009). Alongside these developments, other significant policy changes have occurred. For instance, the launch of Kenya Vision 2030 (RoK, 2007b), the development and implementation of the Strategy for Revitalisation of Agriculture (SRA) (RoK, 2005a), the development and launch of the draft Science, Technology Innovation (STI) Policy and strategy (RoK, 2007a) and the recently launched National Biotechnology Awareness Strategy (BioWARE) (RoK, 2008b). The SRA operationalises the Economic Recovery Strategy for Wealth Creation (ERS) (RoK, 2003a) and gives priority to the agriculture sector (RoK, 2005b: 54). The STI policy and strategy operationalises the Kenyan Vision 2030.

These recent initiatives outline vividly the role of agricultural research and some specifically identify biotechnology as one of the new science and technologies that need to be supported for the anticipated robust agricultural system (RoK, 2005a; RoK, 2006a; RoK, 2007a). However, it largely remains unclear how this is going to be advanced within the knowledge intensive biotechnology sector towards meeting the Millennium Development Goals (MDGs) as well as benefiting the resource poor farmers as one of the overall goals of most of these policies (cf RoK, 2005b).

## 2.3 Evolution of modern biotechnology and biosafety regulatory regime

Modern biotechnology has revolutionised many sectors including agriculture and embraces a wide range of applications including tissue culture, markers assisted selection and genetic engineering (GE). All these are being applied in Kenya, but the latter is the focus of this study. Just like many African countries, GE is relatively new, but GE products have been handled indirectly through trade in form of food aid (Kagundu, 2008).

Agricultural research and development (R&D) has long been recognised as central to knowledge creation, technology development and innovation. During the pre-independence period, the R & D agenda was set by the British colonial government, which recognised the importance of S & T in agricultural production (Ochieng, 2007). It is not until early 1990's that biotechnology innovations in form of tissue culture received considerable attention (Wambugu, 2001). Actual work involving advanced GE commenced in 1991 when Kenyan scientists went to USA and in collaboration with scientists there, engineered a virus resistant sweet potato (Odame *et al.*, 2002, 2003). Thereafter in 1998, the transformed plants required regulatory approval for this research to continue in Kenya. Actual process of regulatory process and implementation had commenced prior to 1998 (see Appendix 6).

To date, six GE R & D initiatives have been evaluated in public institutions in conjunction with local and international partners (Table 1 & Box 1). As these tabulations show, all these trials have been implemented under containment either in the laboratory, greenhouse or open confined field trials (CFTs)<sup>5</sup> under quarantine. The crop activities include *Bt* maize and *Bt* cotton engineered for resistance to insect pests,

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<sup>5</sup> This is a field trial of GM plants not approved for general release in which measures for reproductive isolation and material confinement are enforced in order to confine the experimental plant material and genes to the trial site (Halsey, 2006:4)

cassava for resistance to viruses and sorghum for resistance to striga weed. The recombinant rinderpest vaccine initiative targeted control of rinderpest disease in cattle and other viruses in small ruminants. Other initiatives are in the pipeline for example the sorghum fortified with nutrients funded by the Bill and Melinda Gates Foundation through the Africa Harvest Biotechnology Foundation International (see [www.africaharvest.org](http://www.africaharvest.org)). Since the approval of the first transgenic crop- the sweet potato in 1998, no product has reached the farmers and the furthest the biotechnology activities have gone towards a product is the CFTs (see Box 1).

These research activities are however under government control through the interim governance that has existed since early 1990's. In addition, although this was not clearly provided for in the regulatory instruments prior to the Biosafety Act, all interested investors/persons needed to partner with a government research or academic institute.<sup>6</sup> The Biosafety Act 2009 (RoK, 2009) however removes this restriction and recognises an applicant as "a person submitting an application" and does not state whether this person should do this collaboratively or not. It can be said that the partnering requirement ensuring government control has been implemented effectively, since all the six research trials were licensed through the Kenya Agricultural Research Institute (KARI)<sup>7</sup> and Kenyatta University (KU), and the principal investigators have been scientists from public institutions.

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<sup>6</sup> Interviews with ARp-PS2 and ATBp-PS5.

<sup>7</sup> KARI is the main public agricultural research institute in Kenya and is mandated to conduct relevant agricultural research. Five of the six GM trials (and all the field trials) have been conducted at approved biotechnology confined quarantine facilities within KARI.

**Table 1: Modern crop biotechnology innovations in Kenya (as of Dec 2008)**

GE Activity	Initiative trigger/trait	Status	Collaborators
Sweet potato engineered for disease resistance-Feathery mottle virus.	-The virus coat protein gene availability from Monsanto. -Diseases attack causing low yields.	Contained laboratory & CFTs	KARI, Monsanto, ABSP, ISAAA, Michigan state university, Kenyan universities.
<i>Bt</i> maize-IRMA project engineered for resistance to insects-African maize stem borers.	- <i>Bt</i> technology availability from Syngenta. -Pests infestation in particular Maize stalk borers.	Contained laboratory, greenhouse & CFTs	KARI, CIMMYT, Syngenta, Rockefeller Foundation, USAID, Kenyan universities & Monsanto. <sup>8</sup>
Cassava engineered for Cassava Mosaic Disease (CMD) resistance-African cassava Mosaic virus & East African cassava mosaic virus.	-Disease infestation in particular the CMD reducing yields significantly. -The coat protein gene availability from Monsanto.	-Contained laboratory & screenhouse -Application has been pending for a CFT.	KARI, Danforth center-USA, USAID, Cornell University-USA, ISAAA, Kenyan universities.
<i>Bt</i> cotton engineered for Insect resistance-cotton bollworms (Bollgard I & II).	-Declining production performance. - <i>Bt</i> Technology availability from Monsanto. -Pests infestation in particular African boll worms.	Contained greenhouse & CFTs	KARI, Delta-pine South Africa, Monsanto, KIRDI, ISAAA.
Transgenic sorghum for resistance to striga parasitic weed.	-The availability of a collaborative research grant. -The persistence of parasitic striga weed in cereals growing areas in Kenya.	-Contained laboratory & screen house. -Proof of consent. <sup>9</sup>	Kenyatta University (Kenya), University of California Davis (USA).

**Source:** Compiled from primary and various secondary sources. See abbreviations on pages ix-x.

**Box 1: Field trials discussed by the NBC or conducted in Kenya as of Dec 2008**

- ***Bt* Maize**  
Several field trials have been conducted successfully. The results have shown resistance to *Chilo partellus*, a stem borer prevalent in the lower maize growing zones and less protection over the *Busseola fusca* prevalent in the major maize growing zones. Efforts are being made to address this problem using event MON 89034 from Monsanto, perceived to be effective against this pest.
- ***Bt* Cotton (Bollgard I & II)**  
Three field trials have successfully been conducted. The first one used Bollgard I while the subsequent ones have been testing Bollgard II which is perceived to be superior in terms of controlling boll worms.
- **Transgenic sweet potato**  
KARI scientists transformed initial varieties in USA. The trial was purportedly a flop, which is blamed on the wrong choice of varieties (interviews with RSIn-GP9, TAN-NSS2 and PRp-PS4). Research still continues at a slow pace under containment in the laboratory. Other scientists and partners have since joined in the implementation of the project.
- **Transgenic cassava**  
The trial was approved for containment in the greenhouse. An application for a CFT was discussed in several NBC meetings but was denied approval after the applicant failed to provide non-target environmental data (interview with ATp-PS3; NBC minutes).
- **The recombinant rinderpest vaccine**  
Successful on-farm trials were carried out in 2002-2004, at KARI Kiboko research station. They were to test the efficacy against rinderpest disease and safety of the vaccine in the African cattle. The trial still continues under laboratory confinement in a small scale (interview with RSPu-GP7).

<sup>8</sup> Monsanto is the recent entrant into IRMA project through provision of events MON 810 & 89034. The latter has two genes perceived to be effective against stem borer prevalent in the main maize growing zones (personal communication with KARI scientists).

<sup>9</sup> This project was for proof of consent as part of a PhD student's research work and had no immediate plan for commercialisation (interview with RSAC-GP5).

### ***2.3.1 Biosafety regulation in Kenya***

#### **2.3.1.1 Regulatory mechanism**

Many interviewees perceived the biosafety regulatory regime to be the only way of balancing the opposing and diverse views held by both proponents and opponents of the GE technology (see Chapter five). Biosafety therefore encompasses the regulatory mechanisms that the government has put in place for the governance of GE activities.

Kenya signed and ratified the Cartagena Protocol in May 2000 and January 2002 respectively. This further obligated the government to put up regulatory structures to operationalise it. Article (16) of the Protocol and Article (8g) of the Convention on Biological Biodiversity (CBD) provide for establishment of appropriate mechanisms to regulate, manage and control risks associated with Living Modified Organisms (LMOs). The protocol emphasises on risk assessment (RA) and risk management, and provides guidelines to achieve this (Annex III). There are several ways in which risk identified during RA can be managed, e.g. confinement, restricted use, provision of guidance, technical advice and record keeping (Halsey, 2006).

As in many other countries, a “sound science” or “science-based” approach to decisions pertaining to modern biotechnology regulation is the “official approach” to regulation in Kenya. This is illuminated in the various obligations, official and non-official policy documents that guide the regulatory process (see Table 2). The legal authority associated with each instrument qualifies it as binding or non-binding. The binding instruments are based on the obligations that each confers in terms of implementation and legal administration. They include those international agreements that Kenya has signed and statutes of parliament that incorporate general regulatory issues like plant protection or environmental monitoring. The statutes however fall under mandates of different regulatory agencies. The unofficial or supporting guidelines can be termed as

non binding as there is no legal power bestowed upon implementation. It can be said that they were drafted to facilitate the regulatory process including trials management.

**Table 2: Binding & non-binding instruments for biotechnology regulation relevant to environmental safety**

<b>Policy instrument</b> <i>(see abbreviations on pages ix-x)</i>	<b>Relevance</b>
<b>International and binding</b>	
CBD (1992)	Governs the conservation of biological diversity & the sustainable use of its components.
WTO-SPS (1994)	Provides guidelines for regulation of products in relation to sanitary and phytosanitary concerns that can affect trade.
FAO-IPPC (1997) & ISPM No. 11 (FAO, 2006b)	Provide common and effective action to prevent the spread and introduction of pests of plants and products, and to promote measures for their control. ISPM No. 11 in particular deals with pest risk analysis for quarantine pests, including analysis of environmental risks quarantine and LMOs.
The Cartagena Protocol to the CBD (Cartagena Protocol, 2000)	Provides guidelines for “ensuring an adequate level of protection during the transboundary handling of LMOs that may have adverse effects on environment and human health” (Article 1).
Codex and OECD guidelines <sup>10</sup>	Used sparingly during risk assessment audit of GE applications as reference on food safety and substantial equivalence aspects respectively.
<b>Local and binding</b>	
The Science & Technology Act of 1980 (RoK, 1980)	It provides for establishment of the NCST “to advice upon all matters relating to the scientific and technological activities and research.” This provided NCST the early legal mandate to coordinate drafting of regulations of 1998.
The Plant Protection Act (Cap 324) of 1962 (revised in 1979)	Provides for “prevention of the introduction & spread of diseases destructive to plants.” Enforced through KEPHIS.
The Seeds and Plants Variety Act (Cap 326) of 1977 (revised 1991)	Confers power to regulate transactions of seeds (import & performance evaluation) including granting of proprietary rights to breeders. Enforced through KEPHIS.
Environmental Management and Coordination (EMCA) Act of 1999	Provides for management of environmental policies through establishment of NEMA for enforcement purposes.
The Environmental (Impact & Audit) Regulations (EIA), 2003	Provides guidelines for EIA of all projects likely to have a negative environmental impact (Article 3) under the EMCA Act.
Biosafety Act 2009 (RoK, 2009)	Provides for regulation of activities in GMOs through establishment of the NBA.
<b>Local and non binding</b>	
The Monitoring and Inspection manual (NCST, 2006a)	Provides broad monitoring & inspection guidelines for both animals and plants.
The draft regulations for conduct of CFTs for GE crops (KEPHIS, 2004a)	Provide for specific management measures of a CFT, including confinement measures for selected crops and is accompanied by standard operating procedures (SOPs) for inspectors and trials managers (KEPHIS, 2004b). Enforced through KEPHIS.
Guidelines for handling requests involving GMOs in Kenya (NCST, 2006b)	A resource manual for guiding the NBA in handling & evaluation of GMOs applications. It provided for the NBA even before the Biosafety Act that establishes the NBA was enacted.

**Source:** Various secondary sources that include the mentioned statutes and guidelines.

<sup>10</sup> OECD and Codex guidelines stress on science based risk assessment protocols in line with the substantial equivalence (OECD, 2007; Codex, 2003).

At the early stages of biotechnology research activities, Kenya opted to use the existing infrastructure, the Science & Technology Act (RoK, 1980) to institute regulatory mechanisms through the drafting and adoption of the *Regulations and Guidelines for Biosafety in Biotechnology in Kenya* (RoK, 1998; and the revised version, RoK, 2003b). There have been concerns that these regulations came long before the biotechnology policy and have not been legally binding as required by the law.<sup>11</sup> In an effort to legalise the regulations as well as the biotechnology activities, *the National Biotechnology Development Policy* was drafted and later approved in 2006 (RoK, 2006a). This was followed by different versions of the biosafety bill which became law in Feb. 2009 (RoK, 2009). These three policy instruments are the heart of this thesis as the major policy outcomes of the evolution of the regulatory process discussed substantively further below. But first, these biosafety instruments are discussed briefly and revisited later in Chapter five.

***Regulations and Guidelines for Biosafety in Biotechnology in Kenya (1998) and the revised version (2003):*** These regulations have since been implemented in regulation of the biotechnology activities to date. They served a dual purpose, promotion of biotechnology science and protection of citizens concerns about risk associated with use of the science. In other words, they intended to enhance safe application of biotechnology while facilitating advancement of technological innovations initiated then through Kenya Agricultural Research Institute (KARI):

*“Regulations and guidelines should be effective in encouraging the use of new products, and for ensuring human health and environmental safety...are intended to ensure that Kenya benefits from the products of biotechnology with minimum risks to public health and environment.” (RoK, 2003b: 24)*

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<sup>11</sup> In a normal situation, a policy should precede a law. Consequently, regulations and guidelines are appended to the law as implementing instruments (interviews with LABp-NS8 and LAEp-NS9).



Both 1998 and 2003 versions are concerned with science transfer as opposed to technology transfer. The major provision is the administrative management of the GM activities through the establishment of the Institutional Biosafety Committees (IBCs) and the National Biosafety Committee (NBC). The regulations require that all institutions intending to engage in GM work must establish an IBC. Its role is to advise the respective institution in drawing up proposals that meet the biosafety measures to the satisfaction of the NBC. In addition, it is to advise the respective institution on any technical issue that should be brought to the attention of the NBC. Following the approval of these regulations, KARI IBC was formed and later ICIPE IBC (Traynor and Macharia, 2003). However, other IBCs have since been established (e.g. ILRI, Kenyatta University and KEMRI).

***The National Biotechnology Development Policy (2006):*** The policy was the first legal attempt by the government to charter a roadmap for biotechnology development in Kenya. It was adopted in 2006 without any public resistance, although it was felt that it should have come before the regulations as this is the routine with other policies.<sup>12</sup> It paved way for the creation of an administrative and legal framework for biotechnology development and use. Some of the key objectives of this policy relevant to this study are:

- creation of enabling administrative and legal frameworks for biotechnology development and commercialisation environment.
- support the development and retention of human resources in science, innovation and biotechnology.
- stimulate collaboration among public, private sectors and international agencies in order to advance biotechnology both locally and internationally.
- promote public understanding of the potential benefits of biotechnology.

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<sup>12</sup> Interview with TRTp-NSS3; see also Sander (2007).

The policy emphasises the importance of biotechnology application in addressing major challenges that hamper realisation of full economic potential in agriculture sector. It recognises that technological developments must be translated into innovations for the country's national benefits through conducive policy strategies. It further acknowledges the multi-sectoral nature of biotechnology in terms of institutions that promote, implement and regulate biotechnology, which calls for continuous re-alignment of existing policy instruments to accommodate the new science. One noticeable point regarding this policy that is also evident in the regulations and guidelines is the emphasis on precaution in the adoption of biotechnology. The policy therefore provides a roadmap for the biotechnology activities but based on the identified need to regulate them.

***The Biosafety Act (2009):*** This Act seeks to operationalise the Cartagena Protocol. The scope and other provisions are discussed in Chapter five. The controversial developments surrounding its formulation over the years are at the centre of this thesis. Harsh (2005) reports similar controversies but up to 2005, however, the current study shows that these controversies escalated after 2005. Appendices 7 and 9 capture some of the main developments, revealing the dynamics that include the engaged different actors and the nature of engagement, and details the different forms of public and policy makers' engagement between 2002 and 2009. Within this period, various versions of the biosafety bill were drafted and discussed before the final version (RoK, 2008a) was approved to become an Act. Meanwhile, regulations to be appended to the Act are being drafted under the Program for Biosafety System (PBS) support.<sup>13</sup>

### **2.3.1.2 Conclusion with respect to the regulatory mechanism**

The overall regulatory mechanism discussed here portrays a picture that suggests that the regulatory process has relied upon existing legislation for implementation (for

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<sup>13</sup> [www.isaaa.org/kc/cropbiotechnologyupdate](http://www.isaaa.org/kc/cropbiotechnologyupdate) accessed on 12 Dec. 2008.

example the binding local instruments in Table 2). This perhaps contradicts what has widely been reported by some scholars regarding how the existing biotechnology research activities were advanced under a legal vacuum (cf Wakhungu and Wafula, 2004).<sup>14</sup> The main instruments analysed here (and in details in Chapter five) however give further context to the thesis in various ways. For instance learning, knowledge production and use amongst actors that characterised the regulatory phases discussed further on is embedded in these statutes. It is also important to note that, although the biotechnology policy is not considered to be a regulatory instrument in this thesis, it legally established a foundation upon which regulatory instruments prior to the Biosafety Act and the Act itself are anchored.

### **2.3.1.3 The interim structure for GMOs governance (as of Dec 2008)**

#### **i. Multi-sectoral mode of governance**

Prior to the approval of the Biosafety Act 2009, the governance of modern biotechnology in Kenya had adopted a multi-sectoral approach involving many institutions and sectors. These actors include different ministries and different regulatory agencies (see Table 3). This study focused on environmental biosafety and therefore the **highlighted institutions** and policy **instruments** have been instrumental in the regulation and management of the GE trials. However, beyond confinement, and with the approval of the Biosafety Act, 2009, it is anticipated that the other regulatory institutions will get engaged in a greater magnitude.

As indicated in the table, all the respective government departments or institutions have their respective mandates that touch on biotechnology or GE products in various ways. KEPHIS for instance has been very instrumental in directing the five crop related regulatory activities empowered by a number of legal and supporting regulatory

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<sup>14</sup> This contradiction is revisited in Chapter five, section 5.3.1.

instruments. It is therefore not surprising that many interviewees linked some regulatory challenges discussed below to the enforcement style of KEPHIS.<sup>15</sup> The department of veterinary services is responsible for regulation of animal related activities including recombinant vaccines and was instrumental in the regulatory approval and implementation of the recombinant rinderpest vaccine. The Agricultural Sector Coordinating Unit (ASCU) under the ministry of Agriculture was instrumental in coordination of two key activities: the drafting of the Strategy for Revitalisation of Agriculture (RoK, 2005a) mentioned in section 2.2, and the public awareness tool, the National Biotechnology Awareness Strategy (BioAWARE) discussed in Chapter six, section 6.3.2.

Currently, all the involved government actors and other non governmental players involved in GMOs governance<sup>16</sup> are brought together as a Committee (NBC) under the umbrella and coordination of the National Council for Science and Technology (NCST)<sup>17</sup>, which serves as a secretariat to this committee. This coordination role will be taken over by the proposed National Biosafety Authority (NBA). It is currently not clear how the NBA will operate and this remains to be seen during the actual implementation of the Biosafety Act, 2009.

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<sup>15</sup> Interviews with RSPu-GP1, RSIn-GP2, RSPu-GP4, RSAc-GP5, ATBp-PS5, RSPu-GP8, TAN-NSS2, TAR-NSS1, TRTp-NSS3 and ATp-PS3.

<sup>16</sup> Since the initiation of a biosafety system in 1998, the constitution of the NBC has been changing (see Appendix 8). Several reasons may be attributed to this, for instance the changing regulatory terrain discussed in section 2.4.

<sup>17</sup> NCST was established by the Science and Technology Act (Cap 250) of the Laws of Kenya (RoK, 1980) to “be the national reference centre for policy and advisory services in the scientific and technology services” Its coordination mandate is spelt out in Article 4.

**Table 3: Government institutions with relevant mandates in agricultural GMOs governance**

Ministry <sup>18</sup>	Agency	Legislation/Policy
<b>Ministry of Higher Education, Science Technology (MOHE,ST)</b>	<b>NCST</b>	<b>RoK, (1980); NCST, (2006a, 2006b)</b>
	<b>NBC</b>	<b>RoK, (1998, 2003b)</b>
	<b>Proposed NBA</b>	<b>RoK, (2009)</b>
<b>Ministry of Agriculture (MOA)</b>	<b>KEPHIS</b>	<b>PPA, SPVA, Legal Notice No. 305, ISPM No. 11 of IPPC (FAO, 2006b) and KEPHIS, (2004a, 2004b, 2005).</b>
	<b>ASCU-Research &amp; Extension group</b>	<b>RoK, (2005a); RoK, (2008b)</b>
	<b>PCPB</b>	<b>PCPA of 1982</b>
Ministry of Environment & Natural resources	NEMA	EMCA Act 1999; The Environment (Impact & Audit) Regulations, 2003.
Ministry of Trade and Industry	KEBS	Standard Act of 1974; FDCSA Act of 1965; Draft Code of Practice for handling GMOs; Codex guidelines on GMOs.
	KIPI	Industrial Property Act of 2001
Ministry of Public Health & Sanitation (MOPHS)	Department of Public Health	FDCSA Act of 1965
<b>Ministry of livestock</b>	<b>DVS</b>	<b>Animal Disease Act of 1965</b>

Source: Adapted from Harsh (2005) with modifications.

## ii. The NBC interim governance as a boundary organisation

The NBC has been acting as a boundary organisation overseeing the implementation of the biosafety regulations (boundary objects) that govern the conduct of all actors, including scientists and institutions involved in GM R & D work in Kenya. As a boundary organisation, it has been articulating two major roles:

- Assessment (including risk assessment) and decision-making processes pertaining to GE activities.
- Coordination of development of the regulatory instruments.

### *Assessment and decision-making*

The major role of the NBC has been to receive, discuss and review GM applications with a view of making science-policy oriented decisions. This process has been

<sup>18</sup> Other acronyms used in this table: FDCSA-Food, Drugs & Chemical Substances Act; PPA-Plant Protection Act; SPVA-Seeds & Plant Varieties Act; PCPA -Pest Control Products Act (see other abbreviations on pages ix-x).

coordinated through NCST as the secretariat to the committee. Figure 2 below gives an overview of how this process is articulated. As illustrated by this diagrammatical presentation of the process, key regulatory agencies and Institutional Biosafety Committees (IBCs) are enlisted to enhance the regulatory approval process in various ways. Preliminary risk assessment (RA) commences at the compilation of the regulatory dossier by the applicant (responsible scientist) which is further vetted by respective IBCs before submission to the NBC for rigorous RA audit.

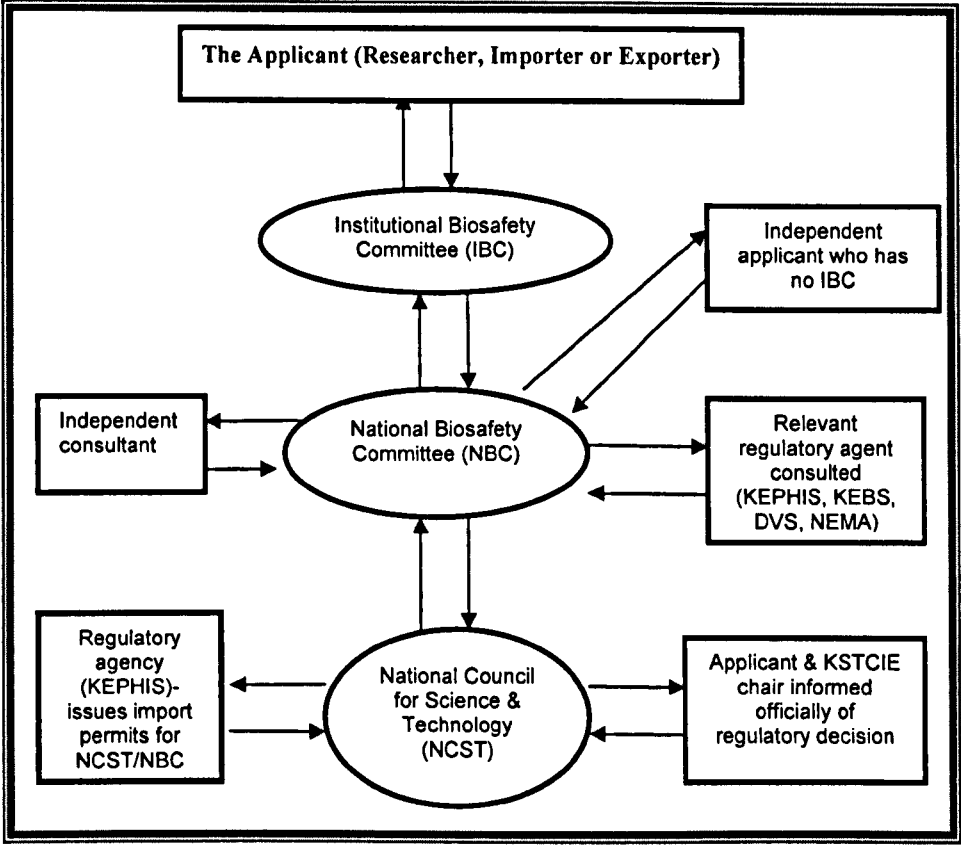
At the NBC, the actual RA and decision-making process takes into consideration the suitability of containment facilities to undertake GE work and requisite RA audit conducted by NBC members, and sometimes experts from regulatory agencies and subject specialists from academic institutions.<sup>19</sup> Decision is communicated by NCST to the respective regulatory agency for action in relation to further administrative matters [like discussion of application by other ministerial committees like Kenya Standing Technical Committee for Imports and Export (KSTCIE) and issuance of permits]. One issue to note from this diagram is the presence of the KSTCIE, a committee chaired by the Director of Agriculture with all its other deliberations being coordinated through KEPHIS. This tends to confuse what would be an “official, all biotechnology activities” approval process as purported, and a question arises as to whether this standing committee serves all institutions and all biotechnology applications, and whether this would generate institutional tensions.

It seems from this diagram that players in the regulatory arena conceptualise biotechnology narrowly through crop agricultural innovations and perhaps the reason why KEPHIS and related institutional arms dominate the interim process. It may therefore not be surprising that many interviewees perceived the decision-making

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<sup>19</sup> Interviews with ATp-PS3, BIp-PS1 and PRp-PS10.

processes implemented under the interim governance to be characterised by both shortcomings and positive attributes discussed in details in Chapter five.



**Figure 2:** Interim approval process of biotechnology activities (Source: Handbook for Policy Makers, 2007). See abbreviations on pages ix-x.

*Coordination of the development of regulatory instruments*

The other role of the NBC is to coordinate development of regulatory instruments under the guidance of the NCST (RoK, 1998). Members of the various technical taskforces involved in the drafting of the regulatory instruments were drawn from the NBC members or from the scientific and legal fraternity. Those outside the NBC had to undergo vetting and commendation from the committee.<sup>20</sup> The role of scientists in the formulation of regulatory instruments forms a substantive analytical part of the entire thesis and in particular Chapter six.

<sup>20</sup> Interviews with ATp-PS3, BIp-PS1, ATBp-PS5, ARp-PS9 and minutes of various NBC meetings.

## **2.3.2 Challenges confronting the evolving agricultural research and modern biotechnology governance terrain**

### **2.3.2.1 Contract research**

It is widely argued that biotechnology is a key tool for 21<sup>st</sup> century sustainable development (cf Bananuka, 2007). However, most people agree that this may remain a dream unless certain challenges are addressed that include political support through provision of incentives for research and regulation (cf *Ibid*,:30; Echeverria and Beintema, 2009). In Kenya, government support for S & T including biotechnology R & D has been minimal (Beintema *et al.*, 2003; Odame *et al.*, 2003). However, the government has reiterated the importance of agriculture in economic growth (see section 2.2) and with the new reforms, it has pledged to increase funding for agricultural R & D within the research institutions by 2% of the national Gross Domestic Product (GDP) through the Ministry of Agriculture by year 2010 (RoK, 2006b:66; RoK, 2005a:6). This is however interpreted as a mere statement of intent and previous commitments have not been honoured. For instance at the time of the field work, the Executive Secretary to the NCST lamented that the government committed to increase its budgetary provisions for research to 1% of the GDP in 1982/83 but never honoured its commitment.<sup>21</sup>

The dwindling research funds and other policy reforms have encouraged collaborative research, technology development and deployment (RoK, 2005a; KARI, 2005; RoK, 2007a). Although the government continues to fund public agricultural research, a significant support comes from donor organisations (Beintema, *et al.*, 2003:5). Kenya Agricultural Research Institute (KARI) being the major research institute involved in modern biotechnology research (and the only one undertaking open field trials) has undergone significant restructuring in response to these reforms and challenges. KARI

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<sup>21</sup> Interview with BIp-PS13.



had to revise its strategic plan first published in 2000 to accommodate the collaborators needs:

*“KARI's collaborating partners within CGIAR system have revised their strategies, indicating areas of future collaboration with NARS” (KARI, 2005: 1-2).*

These changes have contributed to a rise in contract research characterised by increased donor funding (Beintema, *et al.*, 2003:5; Frempong, 1999). For instance all the agricultural GM trials are being undertaken through Public Private Partnerships (PPPs) arrangement (Ayele *et al.*, 2006).

Collaborative or contract research has a historical link and is not new in KARI. In late 1980's KARI was already involved through signing of Memorandums of Understanding (MOUs) in contract research in maize breeding with Kenya Seed Company (KSC), tissue culture flower production with Oserian Development Company, and in sugar research with Kenya Sugar Authority (now Kenya Sugar Research Foundation-KESREF) (Beintema, *et al.*, 2003:5). A lot has also been documented regarding the tissue culture bananas contract research (cf Smith, 2004). As the current study suggests, in the case of modern biotechnology, the nature of contractual research is still under-researched and is undergoing changes at unprecedented rate due to the evolving institutional and regulatory contextual issues that are discussed throughout the thesis. What seems to lack is information on how scientific social actors have been responding to the institutional changes associated with regulation of biotechnology science.

### **2.3.2.2 Biotechnology and biosafety capacity**

According to Bananuka (2007), the need for regulatory capacity evolves alongside an operational biotechnology sector, and this has been the case in Kenya. Since the biotechnology programme was initiated in early 1990's, capacity in both modern biotechnology techniques and biosafety (human, infrastructural and institutional) has

been built over the years. For instance, a modern biosafety Level II greenhouse has been put up at the KARI biotechnology centre and two open quarantine facilities have been in operation for over five years in KARI, at Mwea and Kiboko. According to a report prepared for policy makers (Handbook for Policy Makers, 2007), the number of scientists trained in biotechnology countrywide has gone up, with 45% of those trained being actively engaged in GE work. In addition, capacity in regulatory institutions like KEPHIS, KEBS, DVS and DPH has been strengthened and as argued in this report, these institutions are in a state to oversee the implementation of biosafety regulations (if the biosafety bill, 2008 was to become a law).

These rhetorical claims were advanced by GMOs proponents, in their endeavour to lobby for the enactment of the bill (see Chapter six, section 6.3.2). However, these capacity building and biopolicy developmental efforts have been collaborative.<sup>22</sup> Despite these milestones, both infrastructural and human capacity remains far from being adequate. This is attributed to several factors among them inadequate government support for research discussed above and lack of regulatory policy environment to spur development (Wafula *et al.*, 2007), that would further encourage and favour capacity building efforts. The increased cross-over of trained scientists from public institutes to international organisations locally and abroad has also contributed to the unsustainable capacity building efforts,<sup>23</sup> a trend which is prevalent in the African region as a whole (Hastings, 2009).

#### **2.3.2.3 Conclusion with respect to challenges and institutional role of actors in the interim GMOs governance**

The interim governance of GMOs activities described in the previous section had empowered the NCST and the NBC to handle all GMOs matters through a multi-

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<sup>22</sup> See Appendix 5 for description of the multiple actors and their various roles.

<sup>23</sup> Interviews with TAD-NSS6 and TAN-NSS2.

sectoral representation. Theoretically, this interim governance seems to have worked if approval of six GE trials is anything to go by. However, interviews with different stakeholders revealed a different picture based on experiences of scientists in biosafety regulations implementation as discussed in details in Chapters five and six.

From the foregoing analysis, it is emerging that various challenges have hampered the evolution of the twin processes - biotechnology innovation and regulatory regime. These relate to partly the technical and institutional capacities, but this analysis does not address an important question related to how the actors (individuals, organisations and related links) deal with the analysed challenges. Further, the implications in terms of how challenges are dealt with are important in informing the dynamics around knowledge use and regulatory policy-making. What would lead us to a better understanding of these questions is investigation of activities and relationships built around the evolution of the twin processes (biotechnology research and regulatory regime). Relationships touch on actors and interactions among them, and are central to this thesis. In addition, it is noteworthy pointing out that involvement of scientists (and other related actors) in the related relationships building dynamics is historically linked to the way both processes were initiated in Kenya (Sander, 2007). This is the subject of the next section.

## **2.4 Actors and relationships dynamics in the evolution of biotechnology and biosafety regime**

In the co-evolution of biotechnology and biosafety developments since early 1990's, four significant phases of the regulatory process can be identified based on the dynamics between actors on the one hand, and the biotechnology and institutional innovations on the other. In this section this co-evolution process is discussed, seeking to illustrate how iterative and non-linear the involvement of scientific community in the regulatory process has been.

This description serves four main purposes. Firstly, it situates the scientific actors in the co-evolution process. Secondly, it makes a case for the important role the scientific community plays, not only in the innovation process but also in the policy process. Thirdly, it highlights the contextual factors that make Kenya unique as a tool for investigating perceptions and practices of scientists and fourthly, it justifies why particular scientific actors were selected for the fieldwork. The last two factors further reinforce the justification of the methodology adopted in this study (see Chapter four, section 4.5).

The argument advanced in this section is that, scientists have been articulating various roles in the regulatory process, but more important is how this is achieved within the diverse knowledge nodes that they directly or indirectly engage with. The complex interactions involved are illustrated in Figure 1 (Chapter one). The different regulatory phases under which the different types of relationships have been built and different roles played out within this setting are discussed below in detail.

#### ***2.4.1 Phase 1 (1990-1998)***

This phase is simply the planning and initiation phase of the regulatory process that commenced with the early biotechnology research agenda. Various actors are involved. The National Advisory Committee on Biotechnology Advances and their Applications (NACBAA) was formed in early 1991 by the Ministry for Research, Science and Technology under the NCST to advice on matters pertaining to national priority setting on biotechnology applications that “could resolve productivity constraints of conventional agricultural methodologies” (Sander, 2007:23). The committee emphasised the need to cooperate to enhance effective biotechnology deployment (Olembo *et al.*, 1995, cited in Sander, 2007:24-25). This implies that it was conceived early as recommended by this committee that biotechnology could only achieve its

objective if actors worked corporately and collaboratively. This therefore marked the beginning of the external funding euphoria and donor dependency that was to characterise future biotechnology activities and regulatory instruments formulation endeavours. NCST was to offer the requisite coordination of the many actors and has continued to do so. This is how NCST became an active focal point on matters of biotechnology and later biosafety policy (Thitai *et al.*, 1996).

In the spirit of collaboration, capacity for biotechnology was enhanced and the role of scientists came to the fore. Through the USAID- Agricultural Biotechnology Support Programme (ABSP), KARI scientists started a collaborative venture on tissue culture. Later this was upgraded to modern biotechnology where two projects were initiated (the rinderpest vaccine and the transgenic sweet potato). The former has not been controversial as the latter although both were initiated at the same time (Sander, 2007). Some interviewees expressed concern that the way biotechnology was popularised by the “early scientists” as a panacea to food security could have aggravated the crop biotechnology controversy.<sup>24</sup>

Analysis of reports of workshops proceedings held within this phase to discuss the draft regulations suggests that, early scientists who got the opportunity to be involved in the modern biotechnology initiation made a case for biotechnology during these workshops (Wambugu, 1996). However, other scientists outside the biotechnology programme argued for capacity building and safe deployment of biotechnology hence made a case for biosafety policy (cf Mbaratha, 1998; Ekirapa, 1996).

Scientists in this phase can be seen to be articulating two roles; as scientific or technical advisors and as policy advisors unified by one goal, to develop a regulatory structure for R & D research. However, the objective was not to enhance safety in application of

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<sup>24</sup> Interviews with RSIn-GP9, RSPu-PS7, RSPu-PS8, TAN-NSS2 and NGOco-NS4.

biotechnology products but to enhance scientific opportunities for both KARI and the government (NCST) (Sander, 2007:42). This implies that KARI interests were not in conflict with the government interests, while the interests of non state partners were not directly regulatory policy related.

The Dutch government (Europe) through the Directorate General International Cooperation (DGIS) funded the drafting of the first regulations. This support was later criticized by analysts from US, arguing that Europe involvement led to a precautionary approach to biosafety regulations and practice in Kenya (Paarlberg, 2001, 2007, 2008). What is not immediately clear is how this influence may have occurred, considering that USA through USAID later became intensely involved in the biosafety policy process (see phase 3). According to the empirical data from this study, this accusation may be linked to the failure of the first regulations to incorporate technology transfer aspects in favour of research or science transfer (under confinement), and which is interpreted in various ways by scientist interviewees (see Chapters five and seven).

Despite these contentions about role of actors and impacts, it is argued that the collaborative effort of DGIS, NACBAA and USAID contributed to learning that resulted into shift of NCST developmental policy agenda to biosafety policy (Sander, 2007; interviews with BIp-PS11 and RSIn-GP9).

#### ***2.4.2 Phase 2 (1998-2005)***

Actual controversies surrounding governance of biotechnology innovation commenced during this phase. It is characterised by actual implementation of regulatory instruments prior to the Biosafety Act which many actors found inadequate as regulatory benchmarks (see Table 8). Consequently, challenges encountered during this phase energised the scientific community to become proactive in the regulatory policy process.

There was one aspect which was not disputed by all the interviewees; that the existing regulations were not legalised as would be expected (see also similar claim by Odame *et al.*, 2003). This may be linked to many factors. First, the circumstances under which the biosafety regulations were found necessary points towards science side pushing the government side (see phase 1). This may imply that the legal implications pertaining to implementation may not have been given critical thought.<sup>25</sup> Second, NCST became the focal point for biotechnology and biosafety but questions have been raised as to whether this is the right institution given that other institutes hold a mandate with regards to agriculture and environmental policy matters<sup>26</sup> (see also Table 3).

The subsequent entering into force of the Cartagena Protocol in September 2003 signalled major policy initiatives (see Appendix 7). However, the ratification of the protocol came after 1998 and the subsequent obligation to operationalise it pointed towards revision of the existing regulations. This became another key motivation for many actors (individuals, organisations and donors) to get involved in the regulatory process.

Three main players are actively involved in this phase but are linked to multiple actors through complex interactions:

- i. ***The Eastern African Research Network on Biotechnology and Biosafety (BIO-EARN) project*** funded by the Swedish Developmental Agency (SIDA) commenced in 1998 with main focus being human and infrastructural capacity building in biotechnology R & D. Consequently, biosafety and biotechnology policy-making were identified as key challenges towards achieving this goal.

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<sup>25</sup> Interviews with LABp-NS8 and LAEp-NS9.

<sup>26</sup> For instance NEMA is mandated by EMCA Act to regulate environmental matters, KEPHIS is mandated to oversee implementation of the National policy on biotechnology (Legal Notice, No. 305 establishing KEPHIS under the State and Corporations Act) as well as regulate introduction of crops that may cause injurious harm to the environment.

Thus, the programme sponsored awareness workshops for scientists, policy makers and private sector aimed at stimulating collaborations (Mugoya, 2007: 9) and other initiatives that resulted into policy materials (cf BIO-EARN, 2003-resource book for biosafety implementation in East Africa). One key factor to note is that activities under BIO-EARN largely involved natural scientists in academic and policy arena, while the information resources materials were intended to impact policy change:

*“The main goal of the resource book is to provide a tool for regional guidelines in biosafety implementation to scientist and national biosafety assessors.”* (BIO-EARN, 2003: i-ii)

It is however claimed that BIO-EARN did not directly impact policy change and the only tangible output is training of PhD students from academic and research institutes (Sander, 2007).

- ii. ***The UNEP-GEF Biosafety Enabling Activity project:*** Kenya was one of the 18 countries that benefited from this project which had two phases. Phase I commenced in 1997 and Phase II in 2002. The latter aimed at securing adoption of a national policy and a law through establishment of a regulatory regime (Traynor and Macharia, 2003). It supported the development of an institutional and legal national biosafety framework (NBF) with the goal of establishing a sustainable and effective biosafety management system, and strengthening the capacity and national infrastructure for handling GMO's in the country. A National Coordinating Committee (NCC) was formed and launched in September 2002 to support the implementation of this latter phase. The NCC consequently formed various working groups and task forces among them the legal taskforce which came up with drafts of the following policy documents; the Revised Regulations



and Guidelines on Biotechnology and Biosafety, 2003; National Biotechnology Development policy and the biosafety bill, 2005.

Sander (2007) claims that, the NCC minimised the role of research scientists in the policy process because its members were drawn from the NBC. Contrasting this view, the findings of this thesis suggest that, in the external activities outside the NCC and the internal activities within the NBC and IBCs, the research scientists were actively involved as policy and scientific experts. Indeed, most interviewees admitted being involved in various ways (e.g. within IBCs, NBC or during public awareness and biosafety workshops).

iii. *The Program for Biosafety System (PBS)* was a renewed initiative launched in 2003 by USAID to support the national biosafety policy and institutional capacity development (see [www.pbs.org](http://www.pbs.org)). It was meant to address the pocket gaps left by the UNEP-GEF project, particularly capacity building of the key regulatory agencies<sup>27</sup> (see also [www.ifpri.org](http://www.ifpri.org)). Early PBS activities were coordinated through NCST and focused mainly on building KEPHIS capacity to enhance the regulation of field trials and training of IBC and NBC members. PBS also engaged consultants to backstop the review of the supposedly cumbersome old GMOs application form that resulted into a revised application for Confined Field Trials (CFTs).<sup>28</sup> These capacity building efforts were aimed at enhancing transparent, proportionate risk based-reviews and efficient regulatory approval process (Jaffe, 2006; Maclean *et al.*, 2002). Some interviewees supporting the role of PBS claimed that, tension between regulatory agencies and research institutes tended to slow the regulatory approvals and hence PBS was stepping in to harmonise the

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<sup>27</sup> Interviews with BIp-PS1, TAD-NSS6 and TAD-NS11.

<sup>28</sup> Interviews with RSIn-GP9, PRp-PS10 and BIp-PS1.

regulatory operations.<sup>29</sup> PBS was later to get involved aggressively in biosafety policy process and in lobbying for the enactment of the biosafety bill (see phase 3).

A critical analysis of dynamics under this phase suggests that the increased activities of actors including donors focused on regulatory policy, a reverse of what occurred in phase one. Financial support, learning and knowledge use in phase one targeted technology development while in this phase, these endeavours were oriented towards policy learning and influence. Consequently, the corresponding scientific activities seem to be heavily masked by the policy hype, with majority of scientist actors assuming policy roles.

#### ***2.4.3 Phase 3 (2005-2009)***

This phase constitutes the climax of controversies surrounding the legalisation of biotechnology research and the interim biosafety regime through the public and parliamentary debate of the biosafety bill versions 2005, 2007 and 2008 (see Appendix 7). It was characterised by proliferation of pro and anti groups (NGOs) who adopted opposing stances demonstrating dynamic activism (see Appendix 6). Two main actors are worthy mentioning at this point. The Kenya GMO Concern Group (KEGCO) that evolved to Kenya Biodiversity Coalition (KBioC) after its membership increased from 12 (as of Sep 2004) to over 30 (as of 2008). It comprises of NGOs from the civil society who were opposed to the biosafety bill (and some against GMOs). The other group is the Kenya Biosafety Coalition (sometimes referred to as Kenya Biotechnology Coalition) discussed in Chapter six, section 6.3.2.3. The latter articulated its goals and interests through wide range of institutionalised policy and scientific networks [e.g. The

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<sup>29</sup> Interviews with TAR-NSS1, TAN-NSS2, ATBp-PS5, RSPu-GP1 and TAD-NS11.

Open Forum for on Agricultural Biotechnology in Africa (OFAB) and the NBC], while the former was more proactive through public and media avenues.

The *USAID* through the Program for Biosafety System (PBS) and International Food Policy Research Institute (IFPRI) is a key actor in this phase. Its activities unlike in the second phase are coordinated through two organisations - NCST and ISAAA-Africenter. PBS in collaboration with NCST is involved in a programme intended to harmonise the regulatory institutions operations in Kenya, thereby streamlining and enhancing their capacity for efficient deployment of GMOs in Kenya including GMOs food (see [www.biosafety.ke](http://www.biosafety.ke)). On the other hand, ISAAA-Africenter collaborates with IFPRI in coordinating the communication component of PBS in Kenya. Under this component, the policy makers, regulators and media, were actively sensitized to make a case for biotechnology, while emphasising the need for a biosafety law.<sup>30</sup> One significant difference between this phase and the others is the increased utilisation of resources, notably information and finances, for the counter and rhetorical activities articulated tactfully to influence policy learning and trajectory (see Chapter six, section 6.3.2).

Another key thing to note is the division among parliamentarians between pro and anti-groups. The pro-group aligned itself with the biotechnology proponents while the anti-group with opponents. The media became the sphere for expression of opposing standpoints as analysed in Appendix 9. Just like phase 2, it seems like activities in this phase were highly politicised with a temporary merger between science and politics on the one hand, and public and politics on the other.

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<sup>30</sup> For instance, journalist interviewed in this study admitted receiving training and exposure to GM fields locally and abroad through ISAAA and ABSF; see also Handbook for Policy Makers, (2007) and Wafula *et al.*, (2007).

The most significant outcome of this phase is the approval of the bill to become an Act, ushering in the era of technology transfer through commercialisation of GMOs, and perhaps more controversies. A parallel counter biotechnology and biosafety bill 2008 was also presented to the parliament for consideration by the civil society but was however rejected in one of the parliamentary sessions. This parallel bill was accompanied by a comparative analysis of the government fronted bill and the civil society preferred alternative counter bill.

The different conflicting outcomes of learning through different and diverse interactions tend to question the nature of influence of the regulatory process. This is investigated further in the empirical chapters.

#### ***2.4.4 Phase 4 (beyond 2009, post enactment of Biosafety Act, 2009)***

This phase may be perceived to have commenced after the biosafety bill, 2008 received presidential assent in Feb. 2009, laying the regulatory structure for GM trials approval, risk assessment (RA) and eventual deliberate release of products of GE technology into the environment. Not so much can be said about this phase for it is still early, however, it is anticipated that the public will be watching to establish the truth of the claims related to GE technology (benefits and risk potential). The Act provides for public education, RA and mechanisms for enforcing deterrent measures, but it remains unclear how these provisions will be implemented. More controversies are envisaged during implementation based on the weaknesses inherent in the approved Act which were identified by interviewees (see Chapter five, section 5.6.2).

#### ***2.4.5 Conclusion with respect to evolution of regulatory phases***

Critical analysis of the different phases of the regulatory path since early 1990's suggests dynamism of actors in relation to cumulative learning, knowledge production and use, and the impact of this knowledge on technological and regulatory innovations.

Understanding this dynamism is important and provides a context for supporting the argument advanced in the entire thesis related to scientific practice, including the cultural shifts and the role of knowledge in influencing the regulatory process.

To conclude the chapter, a number of empirical studies that further provide a context for this thesis with regards to knowledge gap are explored before engaging with the more broad literature review in the next chapter.

## **2.5 Empirical studies on modern biotechnology governance in Kenya**

From a developing country context, a number of studies have been undertaken to establish how different countries are dealing with the challenges inherent in biotechnology regulation.<sup>31</sup> These studies are however fragmented and do not address the core aspect of how the scientific practice is indeed shaping or being shaped by learning and knowledge production dynamics that occur individually or within networks.

A number of scholars have previously investigated controversies surrounding governance of modern biotechnology in developing countries context. Clark *et al.* (2002) demonstrate that governance as opposed to capacity issues has considerably shaped the science and technology (S & T) policy debates in developing countries. Among the things they recommend in order to revolutionalise the debates is dialogue amongst all players in terms of understanding policy implications associated with biotechnology innovation. They suggest that developing countries need to provide their scientists (natural scientists) with an understanding of the social and economic contexts

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<sup>31</sup> □ Researchers from the Institute for Development Studies (IDS) based at Sussex have extensively looked at how these issues are being confronted in developing countries (see [www.ids.org](http://www.ids.org)).

□ Researchers at Innogen ERSC centre, UK have brought to the limelight how biotechnology is being governed in developing countries (cf Ayele, 2007a & 2007b; Ayele *et al.*, 2006; Mugwagwa, 2008 among others- [www.innogen.ac.uk](http://www.innogen.ac.uk)).

□ These studies can be compared to the extensive studies carried out in EU and USA related to biotechnology regulation (See Chapter three, section 3.6.3).

within which biotechnology is likely to develop. This may imply that scientists lack understanding of the social factors that influence their research work but to what extent this may be the case is not clear. This reveals a gap that seems to point towards empirical research related to perceptions of scientists on their related scientific activities like regulatory practice.

Ayele *et al.* (2006) exemplify the fact that Kenyan crop biotechnology activities are public private partnerships (PPPs) originating from outside the public sector. Although this work does not directly concern individual scientists, it sheds some light on the contextual factors under which scientists operate as researchers. The PPPs arrangements put the Kenyan scientists at the centre of the debate in that, one, they are perceived to be initiators of some of these projects and two; they are bound by the rules that cement these partnerships. These PPPs are therefore pivotal in influencing the direction and ultimate performance of expected or desired policy innovations through the choices scientists make, and subsequent behaviour and implications.

The current study may be seen as a continuation of the work of several other scholars who empirically endeavoured to understand the governance issues related to modern biotechnology in the Kenyan context. Odame *et al.* (2002, 2003) attempted to operationalise the innovation system concept by exploring the biotechnology innovation and how it impacts social, political and institutional change. They revealed weaknesses related to biotechnology governance at its initiation stage and demonstrated dynamism of biotechnology innovation process, citing evidence of influence of the process by technology developers (mainly scientists and their allies). They show how the introduction of modern biotechnology presents an excellent arena through which the practices of actors and in particular behaviour of scientists can be analysed as they manage GE trials and consequently adapt to the regulatory demands. However, how the

different institutional and policy dynamics might have impacted the current regulatory practice at both the individual and institutional level is not clear. In addition, how this may have influenced the existing regulatory instruments is also unclear.

Harsh (2005, 2008) identifies informal and formal governance of biotechnology where non state actors (NGOs) take up the space of the government in policy deliberations. He empirically demonstrates the diverse and multiple roles played by NGOs in both biotechnology and biosafety development. Thus, his work offers some insights in understanding the technological and political environment under which scientists operate as individuals or within knowledge networks. However, the role of the scientific community who make up most of these NGOs in the biotechnology and biosafety arena either in their individual and/or institutional capacities is not clear. Moreover, NGOs are rich sources of policy related knowledge but how it is utilised and disseminated is equally important, an aspect that he has not articulated effectively. Further, it is not clear from his work how the NGOs shape scientific practice in a regulatory context. Building on Harsh research, the relevance of time, space and policy subsystem, in relation to the construction of the biosafety bill provides an opportunity through which GE technology governance and evolution of governance mechanisms over time may be understood. Consequently, the revealed dynamics may inform reconceptualisation of policy and practice by relevant actors including scientists.

Sander (2007) looks at the construction of biosafety regulations and guidelines, giving prominence to the role of international donor agencies in this process. Using the actor network theory, his study documents how the activities carried out by different institutional actors influenced, and shaped the context and content of the biosafety regulations that existed before the Biosafety Act, 2009. He reveals the complex interrelationship between the network of actors involved in the construction of biosafety

regulatory instruments. Sander's application of the term actors is more general and although he recognises the importance of science, he does not give scientists prominence in his analysis. Scientists make up most of the institutions and organisations he describes, but a key question that he does not address is how they gain or negotiate authority to become key actors in the policy arena.

## **2.6 Chapter conclusion and summary**

The complex dynamics associated with controversies inherent in the Kenyan biotechnology and biosafety process as the two twin processes co-evolved for almost two decades point towards different roles of scientific actors in the regulatory process. As this analysis suggests, different contextual factors directed the different roles and different styles adopted by multiple actors in articulating these roles. It is however implicit from this snapshot how the involved dynamics interplayed to influence the regulatory path.

The empirical studies reviewed in this chapter also fall short of exposing vividly the role and behaviour of scientists in the regulatory process, perhaps because of the organisational and institutional approach adopted in the analysis of biotechnology governance. Despite these limitations, these empirical studies provide useful insights which the current study builds on to explore empirically learning and dynamics in knowledge production and use, in the context of a complex interrelationship between scientists (in the midst of multiple actors), biotechnology science and regulatory process (see Fig. 1). Meanwhile, Table (4) below presents a summary of issues identified in this chapter and their limitations, and how they relate to this thesis. These issues are the ones taken up in the next chapters, starting with exploration of relevant literature discussed next.



**Table 4: Summary of issues identified in the analysis of the Kenyan context and limitations**

CHAPTER SUMMARY		
Issue	Literature/other secondary sources	Findings and limitations for current research study
S & T policy initiatives and evolution	-Many other S & T policy initiatives exist to support overall agricultural economic development.	-Prior to the Biosafety Act, only few policies addressed regulation of modern biotechnology.
	-Biotechnology & biosafety regime evolving in tandem.	-Biosafety regime evolution is submerged within the broader biotechnology innovation system. -It is implicit from analysis how the co-evolution process shaped behaviour of scientific community and vice versa.
	-Biosafety regulation through interim and multi-sectoral structure. -There are multiple international and national policy instruments guiding biosafety regulation.	-Lack of clarity on role of NBC as a boundary organisation under the interim structure. -Lack of clarity on different legality claims considering the many legal and non binding instruments used in environmental regulation.
	-Multiple challenges confront both technology and biosafety regime evolution.	-Not clear how actors negotiate through these challenges and implications.
	Different sources of resources (e.g. donors) playing a key role in the process.	There is lack of clarity on how the resources influence learning ad the overall regulatory trajectory & policy.
Actors dynamics & evolution of regulatory phases	-The evolution process is multi-actors driven by incremental learning through distinct regulatory phases. -Individual actors' roles submerged within institutional and organisational set ups.	-The interrelationship between biotechnology innovation, actors and regulatory process is complex. -The underpinning learning and knowledge dynamics in relation to actors' roles in regulatory process and nature of relationship between scientific actors and the organisations they are linked to is implicit. -It is unclear to what extent learning occurs, and how knowledge production influences regulatory innovations.
Empirical studies on biotechnology governance	-Most adopt an organisational and institutional approach masking role of social actors.	-There is a knowledge gap linked to scientific practice in the governance or regulatory context.

### **3 Regulation Implementation and Scientific Practice in the Changing Knowledge Landscape**

#### **3.1 Introduction**

Deployment of agricultural biotechnology as a new life science is associated with increased institutional changes which are far removed from the normative and traditional setting under which traditional science & technologies take place. The body of literature discussed here seeks to understand the dynamics associated with these changes in the context of institutional innovations and scientific practice. Using insights drawn from innovation systems, theories of knowledge production, science policy and policy networks literature, this chapter scrutinises how the views and practices of the scientific community are being impacted upon by these institutional changes as they implement biosafety regulations. The analysis is done on the premise that there are some unexplained gaps that are associated with implementation of regulations linked to the knowledge intensive biotechnology innovation and its governance. The overall goal is to explore how responsible governance may be enhanced.

The chapter is organised as follows: Firstly, governance of the new life sciences which is the main concern of this research is discussed. This paves way for the more specific two strands of literature, sociology of science and innovation systems, discussed in the context of knowledge and scientific practice as the main analytical concepts. Secondly, the changing role of science in society is explored. Thirdly, the emerging new modes of knowledge production and the factors impacting change are scrutinized. Fourthly, theoretical concepts that speak about knowledge dynamics and the renewed role of the contemporary scientific community are reviewed. Fifthly, empirical studies related to scientific practice and related knowledge use are presented. Lastly, biotechnology innovation is explored in the context of the changing knowledge production terrain.

## 3.2 Governance in the new life sciences

The different applications of the term governance have been contested both in theory and practice. In this section, this concept is analysed based on how it is applied in the regulatory processes linked to the new life sciences and in particular agricultural biotechnologies. Levidow (2007:22) notes that governance provides “cooperative means to deal with common problems” associated with biotechnology acceptance in Europe. Governance has also been applied in public policy-making to reconcile the role of multiple actors in debating, defining and achieving policy goals. In this respect, the role of the respective governments (albeit theoretically) becomes that of coordinating and steering (Lyall *et al.*, 2009b: 4). Indeed in the new life sciences, there is a clear call to engage a wide range of stakeholders in regulatory policy-making (Tait *et al.*, 2006). Analysis of governance is thus heavily anchored in the decision-making approaches that broadly define governance based on the rules, institutions, practices and power that shape the behaviour of different actors (Harsh and Smith, 2007:252).

### 3.2.1 Challenges in governance of the new life sciences

Despite this clear understanding of what governance entails, there are challenges that confound how decision-making processes are articulated in the new life sciences which include:

- Dynamic growth of the sectors involved that is faster than the requisite institutional structures to support regulatory and policy processes (Tait *et al.*, 2006).
- Strategies for dealing with the tensions emanating from the diverse views of different governance actors, while upholding transparency and accountability (Lyall *et al.*, 2009b).
- Strategies for reconciling the diverse and sometimes conflicting belief systems and interests (Laurie *et al.*, 2009).

- The increasing necessity for scientific and social evidence to guide the decision-making processes (Lyll *et al.*, 2009b), challenging the traditional scientific approach.

These governance challenges notwithstanding, the government control of many aspects of the decision-making processes is still evident (cf. Mugwagwa, 2009, with respect to Africa). This form of government control is particularly manifested in enforcement of safety standards linked to products of new technologies on the one hand and regulatory standards on the other (Tait *et al.*, 2006). Thus, the conflict in reconciling the governance agenda and government control places respective sectors and actors at different points within a government–governance continuum (Lyll, 2007b). Considering its importance, how then can the governance agenda be advanced in the backdrop of the still much needed government control?

With regards to developing countries, governance approaches have been complicated by a number of contextual factors that are social, technical and political in nature, questioning the way governance principles are generally understood (Smith, 2009). The governance agenda in Africa is further challenged by the capacities and the political environment which direct who gets involved in policy processes and how they are engaged (Harsh, 2009; Mugwagwa, 2009). Harsh in particular challenges the role of non-governmental organisations (NGOs) in enhancing the governance agenda, arguing that there are limits that tend to thwart the expected democratic outcome.

In Kenya which is the focus of this thesis, the subject of biotechnologies and governance presents a scenario that deserves critical analysis. This is because transparency and accountability in decision making associated with good governance have been constrained by lack of proper legislation to guide governance actors (Wakhungu and Wafula, 2004; Harsh, 2005). Further, the role of the state in enhancing

effective decision making is particularly challenged by the different power relations among the many stakeholders (Harsh, 2005). This legitimises an empirical analysis of the role of different stakeholders in relation to specific governance role/s.

Globally, a number of approaches have been suggested to enhance the governance principles for policy processes which are inherently political in nature. These include policy networks and advocacy coalitions (see section 3.4.4). The former is understood as “flexible and dynamic alliances” in which the different stakeholders get involved actively in the policy process through various acceptable means (Lyall *et al.*, 2009b; 4; Lyall, 2007b). Coalitions on the other hand are established within policy subsystems that advance the political interests of actors based on their belief systems (Sabatier and Weible, 2007). Integration has also been proposed by various scholars as a way of enhancing governance in the new life sciences (cf Tait *et al.*, 2006; Lyall and Tait, 2005). Primarily, integration attempts to deal with uncertainties and the complex decision-making process while addressing confusion and inefficiencies in dealing with those targeted by regulations. Arguably, this proposal seems to be generally targeting the various affected groups or stakeholders but there are disparities exposed when analysis focuses on specific group of actors and different sectors (cf Chataway *et al.*, 2006).

Lyall *et al.* (2009c) have also offered policy recommendations pertinent for a balanced governance approach, considering the important role of all actors in a government–governance continuum. These include:

- Realisation that governance is a dynamic process that should evolve in a manner that captures this dynamism. This is arguably a difficult task.

- Governance is context dependent and should be evaluated from this perspective.

This allows the emerging strengths, weaknesses and challenges to inform the decision-making process.

To operationalise and implement the foregoing approaches and recommendations, it would be pertinent to consider the diversity brought about by different contexts linked to politics that vary across regions (Smith, 2009a). For instance, the introduction of agricultural biotechnologies in African countries to purportedly address food insecurity has not been without high level local and international mediated politics. This has had an impact on governance based on strategic approaches adopted by different actors within respective countries, places and locations of decision making (Harsh and Smith, 2007).

Another difficulty that may impact the operationalisation of the different proposals is the nascent and evolving nature of the two related processes, biotechnology development and regulatory policies, characteristic of many African countries (Mugwagwa, 2008). In Kenya for example, the two processes have been co-evolving (see Chapter two). This presents a challenge in terms of how different social actors should behave and be concerned about the integration of governance principles in the evolution process. In the new life sciences, regulatory practice and the role of actors form a significant component of the “joined-up” governance-based decision-making processes (Lyll and Tait, 2005:3-17). Despite this understanding, these scholars seem to be speaking to policy makers and actors purportedly targeted by governance policies in a bid to address policy and practice institutionally more generally. Less attention is given to the scientific communities yet they control the requisite institutional or organisational actions. This is an area that needs to be addressed empirically to inform how they should be brought to bear on productive and socially robust decision-making processes.

Perhaps a more important aspect to consider is the form of governance that is experienced and exhibited within networks or coalitions. In the context of developing countries, these high level and interconnected relationships generate knowledge that may influence governance approaches based on the way knowledge is articulated (Harsh and Smith, 2007:256). Looking at knowledge generation and use in the context of biotechnologies regulation would therefore generate useful insights around the role of different actors towards responsible governance. This thesis takes cognizance of the fact that the contemporary scientific community plays a crucial role in directing the development agenda of the science and technologies as discussed in the subsequent sections of this chapter. It thus looks at dynamics of knowledge application through the lens of a heterogeneous scientific community and their interaction with biotechnology development on the one hand, and biotechnology regulation on the other. This consequently enables a more nuanced understanding of the multifaceted interactions and the consequent learning, and suggests how a productive regulatory practice might be better informed.

### ***3.2.2 Challenging role of scientist actors in the governance agenda***

Considering the challenges and limits to governance in the new life sciences, the role of scientific evidence (alongside other forms of evidence) has been put to the test (Tait, *et al.*, 2006: 381-382; Tait and Lyall, 2005:180). How then should experts who constitute a significant part of the scientific community behave towards these unprecedented challenges as they engage in the new life sciences in various ways? Despite clear demonstration of institutional and organisational disruptions that accompany the new technologies (Tait *et al.*, 2006), the strain that individual social actors undergo tends to be taken for granted. This is an issue that has not been given adequate attention in the governance literature alluded to above, which tends to pay more attention to the principles of governance more generally.

Analysis of the context under which actors, such as different groups of the scientific communities, negotiate their way around the complex governance scenario is crucial. This is because in the new life sciences, decision making seems to be occurring at different multiple layers (Lyall, 2007a) with highly interconnected network of actors influenced significantly by the local context (Harsh and Smith, 2007). Further, regulatory practice and related social and institutional accountability as part of the broader governance are embedded in the behaviour of the scientists in the various institutional arenas.

Evidence-based, context-bound practice would go a long way in informing a reflexive regulatory practice that is called for by the multifaceted and multi-actor life science innovations. It would in addition enrich the understanding of the appropriate role of the scientific community vis a vis that of other stakeholders in the government-governance continuum and the overall biosciences policy debates. This is crucial for the institutional and social reforms needed to make the new technologies, particularly agricultural biotechnologies, contribute to meaningful development especially in developing countries (Smith, 2009b; Odame *et al.*, 2003).

### **3.3 Changing role of science in society**

The principles that guided the production of knowledge in the old basic or applied science show science as being constructed in technical, social and cultural realms (Callon, 1995). These principles are however delinked from a practical societal setting and are described as localised and individualised where quality of knowledge is judged through peer review (Gibbons *et al.*, 1994). Thus, there is increased call for reconceptualisation of the relevance of science to the needs of society (Nowotny *et al.*, 2001, 2003). This has opened new ways of investigating how knowledge is actually produced and used in different settings, in relation to different goals that relate to the broader functioning of the society (Jasanoff, 2003). This has changed the simplistic way



of conceptualising knowledge as science based and instead views other social actors as sources of policy usable or relevant knowledge in a situation where “science and society are becoming more porous” and knowledge socially distributed (Nowotny *et al.*, 2001:53). Knowledge produced in this context, unlike disciplinary based knowledge, has been tested by the social, political, economic and cultural context under which it is generated and applied:

*“Socially robust knowledge has three interrelated aspects: it is tested for validity outside as well as inside the laboratory; it is most likely to be achieved by involving an extended group of experts; it results from having been repeatedly tested, expanded and modified.”* (Nowotny, 2003: 155)

These discussions reflect a shift in knowledge production dynamics triggered by complex factors discussed in the subsequent section.

### ***3.3.1 Factors influencing change in knowledge production dynamics***

It is apparent that the new institutional and knowledge production dynamics that have spurred the new role of science in society are seemingly complex and are driven by many factors some of which are explored in this section.

#### **3.3.1.1 Changing knowledge economy and integrated practice**

New forms of technological innovations are viewed in terms of globalised knowledge economy in a process of “globalisation of the scientific and technological communities” (Fukuda-Parr, 2006:2). This type of globalised integration is viewed in the context of collaborations in many aspects. But as Russell *et al.* (2008) argue, this integration is driven by knowledge economy where commercial goal is given a lot of space. This stems to some extent from the changing practice where research is oriented towards the “customer” (Waterton, 2005). This narrow view of “knowledge user” has implications:

- Use of knowledge as something that can be traded implies that knowledge is defined by knowledge consumers and partners (narrowly defined) as the knowledge may have ownership restrictions.
- Evaluation of what constitute “good knowledge” is contested because it is largely directed towards meeting the different clients’ demands.

This creates conflicts and tension as relates knowledge use for public good and imposes certain behaviour on the part of scientists:

*“The blurring of public and private science –science for knowledge advancement and science for commercial gain- has many important ramifications for the contexts for scientific endeavour and, in turn, how scientists must engage with the policy and regulatory process” (Scoones, 2002:6).*

A commercial driven approach defies the problem-focused and integrated approach implied by transdisciplinarity principle as advanced by proponents of Mode 2 (this concept describes a renewed form of practice prompted by the trans-disciplinary setting). However, transdisciplinary practice still remains relevant when addressing complex issues that have societal, economic and environmental concerns.

### **3.3.1.2 Environmental concerns**

Social concerns for environmental have increased and largely relate to management of uncertainty and increased demand for accountability associated with environmental imperatives. For instance, the United Nations Environmental Programme (UNEP) articulation of these issues through the Global Environment Facility (GEF) fund attests to the global and urgent nature of these issues. Moreover, Cartagena Protocol is one convention that is driven by environmental protection agenda. Thus, environmental and risk knowledge is not only local but also transnational in nature (Russell *et al.*, 2008). Environmental concerns have enhanced transdisciplinarity, calling for integration of many disciplines. This has been seen as one way of bringing knowledge created from

various disciplines (natural and social) together in order to confront these problems head on in a systemic way (Miller, 2004). Despite the efforts to standardise ways of dealing with environmental uncertainties, risk assessment and public participation in decision making pertaining to environmental management are contested. These challenges plead for a new way of integration that involves addressing actors' practices:

*"Finding solutions to environmental problems requires not only understanding of environment and threats to it; it also involves influencing the actions and behaviours of multiple societal actors."* (Russell *et al.*, 2008:464)

Application of Mode 2 thinking in environmental sciences may be challenged because of the political context under which the science policy terrain is advanced. This is an area that may present new ways of looking at dynamics related to changing knowledge production terrain in a contemporary setting.

### **3.3.1.3 Informed society**

Knowledge has become fluid and socially distributed triggered by improved exchange of information from the increased knowledge nodes, facilitated by the advanced technological development and the growing venues for information exchange (Nowotny *et al.*, 2001; Gibbons *et al.*, 1994). Consequently, information that is not necessarily knowledge is being generated and diffused. What becomes legitimate knowledge is determined by what the broader society including policy makers consider scientific and policy relevant. This has implications as sometimes the values of science in providing scientific solutions to complex and social problems conflict with some basic social values (Jasanoff, 2003). This calls for new ways of society engagement to uphold best practice guided by evidence-based approaches (social and scientific) as Tait and Lyall (2005) contend.

### 3.3.2 *Emerging linear & non linear modes of knowledge production*

Gibbons and Nowotny using Mode 1 and Mode 2 concepts have described how the traditional basic scientific practice is being replaced by a more integrated practice.

Mode 1 practice mimics linear, individualised and localised characteristics common in research institutes or universities where knowledge is eventually taken up by government or industry. Mode 2 practice on the other hand is transdisciplinary in nature:

*“Mode 2 takes on transient and temporary forms, exhibits fluid contours and provisional norms, and occupies temporary institutional spaces which can accommodate knowledge producers with many different institutional affiliations, either simultaneously or sequentially.” (Gibbons et al., 1994:33)*

The debates about Mode 2 in research have revolutionised discussions around knowledge production depending on the way certain features discussed below are operationalised. These features have provided new ways of investigating societal issues in which many individuals are stakeholders and include:

- Role of “experts” or “specialists” who have acquired different or multiple roles under the principles of “transdisciplinarity” and knowledge produced under “context of application” (Gibbons et al., 1994:148). This relates to research and scientific practice.
- Disciplines and social identities (Gibbons et al., 1994: 148-150). The demand for different types of knowledge (e.g. policy, technical, academic, project and public) has placed the scientific community in a compromising position.
- Learning process and the ultimate way knowledge is used for policy innovations (Sabatier and Weible, 2007).

**Transdisciplinarity:** This principle is a response to a new and integrated way of doing things (e.g. research, policy-making) that promotes trans-disciplinary approach in terms of disciplines, institutions, individual researchers and boundaries. New methods evolve

through an iterative and reflexive process in line with the problem at hand and increased collaboration between players with interest in that particular problem (Russell *et al.*, 2008). The emerging collaborations are perceived to be flexible, fluid and transitory (Gibbons *et al.*, 1994), consultative, socially robust, contextualised, systems-based and adaptable (Nowotny *et al.*, 2001):

*“Mode 2 creates a novel environment in which knowledge flows more easily across disciplinary boundaries, human resources and more mobile, and the organisation of research more open and flexible.”* (Gibbons *et al.*, 1994:20)

The knowledge generated in this context can be said to be problem focused, relevant and easily transferable to stakeholders outside the traditional knowledge nodes like research institutions or universities. It may also be transferable to other non technical organisations like public associations as stakeholders. According to Russell *et al.* (2008), transdisciplinarity at all levels (institutional or individual) is a practice, hence amenable to analysis and change. However, the way Gibbons, Nowotny and their colleagues approach transdisciplinarity is open to criticism because they restrict their approach to mainly technological research activities. They tend to generalise underlying issues that underpin technological practice. For instance, the new life sciences are linked to complex governance issues that may complicate the transdisciplinarity practice because of the context specific institutional structures and policy requirements (Lyll and Tait, 2005; Lyll *et al.*, 2009a). These issues which have been overlooked need to be expounded to give a new perspective and more substance to the concept.

***Knowledge generated in the context of application:*** The way Gibbons, Nowotny and their colleagues debate this feature relates to partnering of both knowledge users and developers in knowledge production for a socially desirable outcome. The site of knowledge generation and the site of eventual use are purportedly tightly linked which seems to be an oversimplification because “context” can be framed or interpreted in different ways. There are many factors that may influence the way a desirable outcome

may be achieved. Uncertainty, politics, values and interests for instance confound endeavours to deal with decision-making processes in the new life sciences (Newell, 2002; Laurie *et al.*, 2009). Thus, knowledge produced in this context cannot automatically be perceived to be legitimately “applied” or desirable. In view of this, knowledge generated in the context of regulations implementation that occurs in tandem with technological developments is also critical since it has implications for socially desirable regulatory practice.

***Reflexivity and changing identities:*** The increased integration and collaboration under Mode 2 practice challenge certain behavioural aspects related to knowledge management. Integration calls for reflexivity where the innovation communities as knowledge suppliers are expected to agree with users. This may be problematic because reflexivity in a trans-disciplinary setting may be constrained by capacities and beliefs (Gibbons *et al.*, 1994:139), individual capabilities and influence by communities of practice<sup>32</sup> as they interact and promote learning (Johnson and Thomas, 2007:46-47). Again the ability to balance and promote both scientific and socially related identities depends on the nature of research, problems at hand and organizational context (Gibbons *et al.*, 1994:139; Waterton, 2005). In the context of regulations implementation particularly in policy formulation, certain social and technical values may constrain reflexive practice (Jasanoff, 2003; Murphy and Chataway, 2005).

***Knowledge flow and increased communication:*** This feature is embedded in the other features discussed above and as demonstrated by Gibbons *et al.* and Nowotny *et al.* it may occur in two ways. Firstly, in the case of the scientific fraternity, codified and tacit knowledge-flow facilitate transdisciplinarity through mobility (in various forms like scientific fora, networks, emails, direct contact etc), changed priorities setting amongst

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<sup>32</sup> Communities of practice are groups of people who have a common interest and are engaged in a shared enterprise, through which they both have, and further develop, a repertoire of knowledge, skills and practices (Wenger, 1998, cited in Johnson, 2007).

scientists and competition and cooperation among scientists as they deal with research related issues.

Secondly, in the case of society, communication of technological knowledge from scientific fraternity to society has been necessitated by the increased societal demand for accountability. What is not clear from these scholars' narrative is how complexities and challenges associated with the two-way knowledge-flow may be dealt with in different contexts like a regulatory context. Scholars who have pursued governance issues in the new life sciences have empirically shown how cumbersome desirable policy instruments for communication and integration have become (cf Lyall *et al.*, 2009a).

**Quality control:** This is one of the implications of the changing knowledge landscape which presents itself as a knowledge management challenge due to varying accountabilities demanded by multiple actors involved (Nowotny *et al.*, 2001, 2003; Waterton, 2005). In Mode 1 research, quality control is upheld through peer review but with Mode 2 research, standardising quality control is problematic as this transcends science and non-science arenas. There has been for instance an increased demand for non-scientific knowledge to legitimise risk assessment process in controversial and contested sciences (Jasonoff, 2003; Levidow, 2007). This is perhaps because the public is losing faith in authority of science to provide convincing solutions to societal problems (Russell *et al.*, 2008; Jasanoff, 1987). This feature presents a new way of investigating behavioural changes related to management of knowledge that is policy relevant like regulatory science.

### **3.4 Understanding knowledge dynamics and actors' practice**

The interdisciplinary approach adopted in review of literature for this study permits exploration of approaches that give a clear and different perspective of scientific practice in the backdrop of the complex factors, and linear and non linear modes of

knowledge production discussed in the preceding sections. This section looks at scientific practice and knowledge dynamics in light of how this has been debated under different key theoretical approaches, exposing the underpinning factors that qualify practice.

### ***3.4.1 Innovation systems: institutions and social actors***

Two interrelated key concepts that have been widely debated under Innovation Systems (IS) literature are learning and knowledge. As Johnson and Wilson (2006:748) contend, learning is the process of knowledge attainment and generation. The two concepts are important in understanding the role of actors in the processes of innovation or development and social change more generally (Johnson, 2007:277). Indeed the IS approach as a framework provides a way of understanding the dynamism of knowledge production (which is both informational and institutional) and its implication for the innovation system (Clark, 2002). A lot of information is generated in a dynamic system such that it becomes important to “identify what is relevant to any specific activity and organise it in a productive way” (*Ibid*,:360). This brings in the social context that qualifies information as knowledge. Oyelaran-Oyeyinka (2005:14-15) further contends that in a dynamic system, there is increased learning characterised by co-evolution of technology and institutions (informal and informal). Consequently, what is co-produced between actors is “usable knowledge”<sup>33</sup> that links knowledge nodes (e.g. research institutions) to “action” nodes (policy makers, farmers and other users) outside the codified forms of knowledge (Kristjanson. 2008:2).

Knowledge and learning are however conceptualised better in an institutional context. But this can be problematic because application of the term “institution” is confusing linked to different interpretations of the terms “organisation” and “institution” used

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<sup>33</sup> Usable knowledge is perceived to be accurate knowledge relevant for policy-making but the process of its production is contested (Haas, 2004).



interchangeably in most cases (Edquist, 1997; Edquist and Johnson, 1997). As Edquist and Johnson (1997) note, organisations diffuse and manage scientific and technical knowledge while institutions direct this knowledge:

*“Institutions are sets of common habits, routines, established practices, rules or laws that regulate the relations and interactions between individuals or groups.”* (Edquist and Johnson, 1997:46)

This definition presents a clear distinction between formal and informal institutions. The formal rules are statute law, common law and regulations while informal institutions comprise of social norms, habits, routines and practices (Oyelaran-Oyeyinka, 2005:7, expounding the definition by North, 1990). This definition brings the “social context” in the whole institutional picture that guides the way agents behave or operate (Coriat and Weinstein, 2002; Nelson and Nelson, 2002). Thus, social actors are key components in the innovation process through the practices they engage in but usually masked by the firm or organizational view.

The IS approach explains how institutions in their organizational forms are the nodes through which social actors engage in knowledge generation and dissemination activities. However it is implicit about how social and institutional elements interplay to shape the innovation process. Indeed such studies in a multifaceted and globalised innovation like biotechnology are few. One such recent study involving Hungarian scientific community shows how learning and knowledge-flow are highly integrated in such a system (Huzair, 2009). Huzair introduces the concept “culture” that enriches the operationalisation of the innovation system concept in a biotechnology innovation context. She argues that culture acquired and institutionalised in the advent of challenges through learning by epistemic communities<sup>34</sup> tends to concretise a system. Cultural dynamics are part and parcel of an evolving innovation system. This may

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<sup>34</sup> Members of an epistemic community belong to knowledge-based groups and share principled and causal beliefs (Haas 1992: 35). As like-minded scientists, they are transmission belts by which new knowledge is developed and transmitted as usable knowledge (Haas, 2004:587).

explain why particular groups of actors may exhibit commonalities in the way they articulate particular issues or activities. Nelson and Nelson (2002) reinforce this argument in their claim that there is a “set of understandings or beliefs” reflected in particular routines. Paying attention to routines or cultural dynamics opens a different way of understanding human/institution interface that has been given less attention in IS literature (Coriat and Weinstein, 2002).

Based on social context, learning and knowledge production can occur in different ways. For instance according to Johnson (2007:277), this can happen as communities of practice engage in capacity building activities through shared learning. The same is likely to occur as epistemic communities engage in policy processes (Haas, 2004). What seems to be lacking in these debates is clarity about social actors’ practices and social change that promote learning and knowledge production dynamics. There is also lack of reference to policy developments in transformative technologies like biotechnologies considering their political and value laden context under which learning & knowledge production occurs (Philips, 2007). Exploring this further would enrich empirical and productive operationalisation of IS concept from a regulatory context as well as from an informal institution perspective which has not been adequately articulated (Edquist, 1997:27-29).

Application of the IS framework in agricultural development by recent scholars has illuminated various features that are relevant to this thesis as highlighted below:

***Actors’ roles and activities:*** The IS framework recognises the diverse and important roles played by individual actors. In the World Bank report (2007:19), actors can acquire multiple roles and as they learn, roles can evolve and their relative importance can change during the innovation process. Hall (2005: 615-616) also share similar views and describe actors as stakeholders.

***Attitudes and practices of actors:*** These are institutions conceptualised as learned behaviours that shape the innovation process. Attitudes and practices determine how organisations respond to innovation triggers like changing policies or technology. They differ across organisations, countries, regions and sectors (World Bank report, 2007:20).

***Patterns of interaction:*** The World Bank report (2007) and Hall (2005) suggest that collaborations and linkages when analysed in their historical and contemporary context may offer insights on their role in strengthening the innovation capacity. It is however unclear whether the same is true with regards to strengthening the policy instruments like regulations that shape innovative behaviour and consequently innovation capacity. Other forms of interactions that promote learning in innovation systems have been debated. Kristjanson *et al.* (2008:20) for instance emphasise the importance of interactions that promote “learning” rather than “knowing” which is an important approach especially in the contemporary science & technologies and the overall complex institutional setting in which they are embedded.

***Enabling environment that comprises of policies and appropriate institutional framework:*** The World Bank report (2007) and Hall (2005) contend that policies shape behaviour thereby interacting with attitudes and practices. Essegbey and Puplampu (2007) note that conducive and enabling policy environment is particularly important for biotechnology because of the social controversies and complexities associated with its governance. This therefore makes research on behavioural patterns important and compels a researcher to ask for instance, which changes in practice would suggest how actors adapt to particular policies?

#### **3.4.1.1 Context for research in actors’ practice from an innovation system perspective**

Institutional change, which is closely connected to learnt practices and habits, is inevitable for any dynamic innovation system (Hall; 2005; Clark, 1995). Evidence-

based research has come up with suggestions on how practice may be improved through revitalized interactions (cf Essegbey and Puplampu, 2007; Hanlin, 2006; Kristjanson *et al.*, 2008). However these recent endeavours still focus on technological innovations and technical change mainly at the micro level and fail to make explicit how knowledge, particularly scientific and regulatory, may be directed (consciously or unconsciously) towards impacting policy innovations. This thesis seeks to explore this area by adopting a systemic view of the Kenya biotechnology innovation system. The scientific community as social actors spur the dynamic changes in knowledge production and institutional learning within and across the system as they operate within institutions and knowledge based groups (e.g. epistemic communities and communities of practice) to which they belong.

### ***3.4.2 Scientific practice and Mode 2 research***

The well-founded IS literature discussed above has pointed towards institutionalised practice that stems from actors' learning but not the intricacies that arise thereof. This section looks at how scientific practice is impacted upon during utilisation of the technical knowledge (codified or tacit) generated from a dynamic and contemporary setting.

The working environments under which the new life sciences like agricultural biotechnology take place have tremendously been transformed towards a trans-disciplinary setting characterised by shifting institutional knowledge landscape (Russell *et al.*, 2008; Lenhard *et al.*, 2006; Gibbons *et al.*, 1994; Nowotny *et al.*, 2001).<sup>35</sup> This shift has also involved social and cultural changes which these scholars do not seem to explicitly expose. Gibbons, Nowotny and their colleagues have convincingly (although not empirically) offered explanation of how the behaviour of social actors alongside

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<sup>35</sup> This shift is purportedly complex, contentious and contradictory. For instance, scientific knowledge is becoming more important yet its authority has been put to test as discussed previously, knowledge is becoming more socially distributed while science faces complex problems that have social and political interests.

related institutional changes has been effected. They claim that what scientific actors have been experiencing is a paradigm shift from Mode 1 to Mode 2:

*“Old paradigm of scientific discovery (Mode 1) characterised by the hegemony of theoretical or experimental science, by internally-driven taxonomy of disciplines, and by the autonomy of scientists and their host institutions – was being superseded by a new paradigm of knowledge production (Mode 2) which was socially distributed, application oriented, trans-disciplinary, and subject to multiple accountabilities” (Nowotny, et al., 2003: 179).*

Transdisciplinary concept is perhaps the main principle which has been challenged and is closely linked to this shift. Since it is a practice (Russell *et al.*, 2008), it instils in actors the need to cooperate in a complementary way. Actors are required to adapt and in the process they assume multiple social identities (Gibbons *et al.*, 1994:139). The challenge for scientists is the management of disciplinary and social identities in this setting. It calls for diverse capacities to manage the complexities involved. Gibbons *et al.* (1994) describe how strenuous this is for scientific actors arguing that radical changes in behavioural practice are needed to adapt to the strains that confront individual researchers:

*“The transformations are sources of stress. Researchers will be faced by an overload as demands generated by Mode 2 knowledge production are added to those produced by traditional forms of discipline-based enquiry. Professional identities are loosened and broadened, scientific careers become more precarious and mobility adds to strains already inherent in any scientific career.” (Gibbons et al., 1994: 146-147)*

In the process of increased integration and collaborations, the scientific community acquires a status that Gibbons *et al.* call “new hybrid communities” that comprise of:

*“...people who have been socialised in different subsystems, disciplines or working environments, but who subsequently learn different styles of thought, modes of behaviour, knowledge and social competence that originally they did not possess” (Gibbons et al., 1994:37).*

They argue that articulating this hybrid role may require researchers to “evolve a wide range of strategies for survival” (Gibbons *et al.*, 1994:23). The authors attribute this shift in behaviour to dwindling research funding and increased competition for the

limited resources. They further argue that for specialists acquiring ability to work within and across internal and external environments, what is important is the ability to move back and forth between these environments (Gibbons *et al.*, 1994:150). But this may not be easy as implied. Lenhard *et al.* (2006:345) in their empirical research on structural change in disciplines found that “old loyalties are fiercely maintained while new identities are created”. But perhaps what is important is the question about implications of these identities shifts for practice. Moreover, the form of shift impacted by the changing knowledge economy may result in positive or negative change.

The description of the shift in behavioural practice as presented by Mode 2 proponents perhaps does not look critically at how knowledge use can significantly be influenced by social and economic differences that have been found to influence contentious policy processes (Murphy and Chataway, 2005). This actually opens up a new perspective of reconceptualising transdisciplinarity and contextualised practice. For instance, it would be important to establish how actors like scientists conceptualise changes in the new cultures of science prompted by particularly the regulatory demands (as opposed to competition for research funds) and how this thinking is linked to the regulatory or scientific practice; and further still what the implications this may have for the knowledge production and use. It is also not clear how different researchers at different research settings may exhibit these changes especially where motivations and context may be different. It may be also important to understand how reflexivity would relate to behavioural change. For instance, is it possible for experts to be reflexive to accommodate opposing interests as is the case with controversial policies? In this regard, a Mode 2 working environment presents underlying tensions and conflict that may not be evident from the surface, even among the scientific community. This is what may need to be exposed empirically, thus opening different ways of re-thinking policy process and practice.

### 3.4.3 *Scientific practice in the science policy boundaries*

The role of scientific evidence in policies regulating new sciences is acknowledged (Scoones, 2002; Lyall *et al.*, 2009a). In environmental policies, science is used by policy makers to legitimate policy actions (Weingart, 1999). In biosafety policy, science is relied upon to legitimise the process for instance in risk assessment (Scoones, 2002; Levidow *et al.*, 2005; Jasanoff, 1990; Cartagena Protocol, 2000: Annex III). This implies that scientific experts are key players in these processes as they seek to explain the uncertainties associated with GE technology and its regulation. But more important is the way they articulate this role in science policy boundaries or boundary organisations which in their institutional form play a mediation role between science and politics (Guston, 2001).

Boundary work as like in science policy boundaries is meant to facilitate social desirability of evidence-based knowledge by demonstrating social accountability, relevance and legitimacy through co-production by actors (Kristjanson *et al.*, 2008: 2). But what it does to science and scientific actors is pose serious challenges and strains that concern social and science identities (Jasanoff, 1987). Ideally, contemporary scientists continue to explore new cultural spaces for science (Gieryn, 1995: 416) in order to uphold their own identities as scientists as empirically argued by Waterton (2005). Boundary work and boundary organisations when viewed from this science policy context tend to underplay the important role played by other forms of boundary organisations like professional groups or lobby groups as knowledge intermediaries. This thesis considers these forms of neglected knowledge nodes as key avenues of relevant science policy knowledge.

Because of their perceived objectivity and neutrality, scientists are entrusted to control the boundary between policy and science without bias (Keeley and Scoones, 1999:7). This has however been challenged by the political nature of science policies (Weingart,

1999) and the value related social factors. Studies have reported unwillingness of scientists to acknowledge that scientific knowledge is socially constructed and therefore value-laden (Jasanoff, 1987; van Zwanenberg and Millstone 2000; Weingart, 1999; Garvin, 2001). The reason behind this may not be clear but Jasanoff (1990) argues that they do this in order to protect their scientific status in society and their role as policy advisors. Perhaps more important is the capacity of scientists to influence regulation which “relates to their ability to frame problems in a particular way and to suggest solutions and appropriate regulatory paths” (Haas, 1990 cited in Newell, 2002: 15). This process is subject to manipulation based on interests, values and different disciplines alluded to elsewhere.

Controversies in science policy debates complicate the process of reconceptualisation advanced by Nowotny *et al.* (2001) towards a socially desirable practice. The challenge is how scientists can construct their views and adjust their scientific practices in relation to the regulatory issues. This is in the light of their ability and freedom to play multiple roles or shift identities in a changing knowledge production terrain. This has implications now more than ever before because of the increased uncertainties about risk, suspicion between players and increased demand for accountability in environmental sciences. For example the increasing commercialisation of science policy orientation of science has raised questions about the kinds of knowledge able to be produced and judged to be relevant in certain specific contexts (Waterton, 2005; Levidow, 2007). However as Nowotny (2003) asserts, it is not the reliability of scientific knowledge that is being questioned, but rather the context of validation and use that bears Mode 1 individualised and localised characteristics.

Conflicts and tensions related to regulation may be perceived to be unproductive with far-reaching implications threatening and challenging the linear and traditional culture of science in many and significant ways. The immediate result of this as asserted by



certain scholars is the threat posed to the scientific cognitive authority and legitimacy in informing policy decisions (Nowotny, *et al.*, 2001; Weingart, 1999; Jasanoff, 1987). This being the case, there is a clear need for institutional reforms (policy and cultural) to accompany the requisite technological, regulatory and policy change. Such reforms would enhance innovative or economic potential, and how science and scientists can contribute effectively to regulatory policy debates.

#### ***3.4.4 Scientific practice in policy coalitions***

Many scholars have tried to illuminate the complex, messy, interactive and political nature of policy process in practice (cf Considine, 2005; Hajer, 2003; Sabatier, 2007; Keeley and Scoones, 1999). Clearly, there are complex dynamics involved that relate to different actors, generation of different knowledge, sharing of knowledge and resources, power dynamics and competences among others. Consequently knowledge generated may impact policy change.

Analysis of learning from a policy process perspective is important for young innovation systems that are still evolving. This is because the focus shifts from analysis of incremental learning that leads to technological change, to analysis of learning (sometimes short lived) that targets policy change. The former is linked to innovation systems and policy networks (Lyll, 2007a) while the latter is linked to policy coalitions (Sabatier, 2007; Hajer, 1995). In addition, the science-policy interface discussed in the preceding section where scientific actors get entangled in controversial regulatory processes makes exploration of dynamics in policy coalitions worth pursuing. This is because public policy controversies particularly environmental policies are driven more by politics and values rather than technical issues (Mazur, 1981 quoted in Weible, 2007:95).

Sabatier's advocacy coalition framework (ACF) and Hajer's discourse coalition concepts have been applied to explain the dynamics of policy change in a political context. They have both strengths and weaknesses that are highlighted below in relation to this thesis. The Advocacy Coalitions (AC) concept is given more weight due to a number of unique features which are relevant to this research.

#### **3.4.4.1 Advocacy Coalition Framework (ACF)**

To get a good grasp of a political dispute, a theoretical framework that focuses on a holistic view of a broader policy subsystem would be appealing. This is because it would take cognisance of the complex and interactive factors that underpin the functioning of such a system. ACF has the potential to explain actors' behaviour and policy outcomes in intense political conflicts over periods of a decade or more (Sabatier, 1993; Sabatier and Weible, 2007). It offers an alternative approach to understanding behaviour of policy actors in a manner that complements other theoretical approaches applied in this thesis.

Advocacy Coalition (AC) concept stems from Sabatier's conception of a policy subsystem which is an "interaction of actors from different institutions who seek to influence governmental decisions in a policy area" (Sabatier 1993: 16; Sabatier and Weible, 2007:192). Actors who constitute a policy subsystem aggregate into "advocacy coalitions" which are amenable to analysis based on their "belief systems". A belief system is "a set of basic values, causal assumptions, and problem perceptions" (Sabatier 1993: 25) while a coalition is "people from a variety of positions who share a particular belief system and who show a non trivial degree of coordinated activity over time" (*Ibid*). Coalitions seek to manipulate institutional rules and actors in order to achieve certain policy goals.

The dynamism of a coalition is dependent upon resources which include money, expertise, technical information, number of supporters and legal authority with the latter being embedded in institutions (*Ibid*,:29). The way these resources are used is important. Technical information for instance is used by actors as they “seek to convince other actors of the soundness of their position concerning the problem and the consequences of one or more policy options” (Jenkins-Smith and Sabatier, 1993: 45). Shared beliefs rather than interests direct the behaviour of individuals within coalitions providing “principal glue of politics” (Sabatier 1993: 27). Sabatier argues that beliefs are more inclusive and more verifiable than interests and that belief systems models are flexible thus able to incorporate individual and institutional interests (*Ibid*,:28). This argument tends to underplay the role of interests and values that drive players in the new life sciences decision-making processes (Laurie *et al.*, 2009).

Unlike policy networks which focus on institution/s like government or public for analysis of policy or institutional change (cf Lyall, 2007a), a policy subsystem is the principal unit for understanding policy change. To assess the influence of actors on a particular policy system, a policy change must be evident. Based on AC approach, a policy change occurs as a result of various factors. One, non-cognitive factors external to a policy subsystem may change components of policy core beliefs. Two, “policy oriented learning” over long periods of time may result from incremental accumulation of information or increased experience of actors. Learning therefore affects the beliefs of actors within the policy subsystem which can lead to major policy change (Jenkins-Smith and Sabatier, 1993: 42). Three, a hurting stalemate which is a situation in which all parties involved in dispute view continuation of the status quo as unacceptable and run out of options and venues to achieve their objectives.

As a theoretical framework, AC is appealing for analysing policy change because it accounts for mobility of specific individuals within institutions or a subsystem and

variation in behaviour exhibited by individuals (Sabatier 1993:25). It creates an environment for players with similar beliefs (regarding a particular problem) to interact cooperatively as opposed to partnering with those of different beliefs. They tend to distrust those with dissimilar policy core beliefs (Weible, 2005).

ACF's unique focus on a particular subsystem opens up additional ways of understanding the knowledge dynamics in a policy process like biosafety regulation. It offers a way of understanding value related factors linked to actors in a political system thus developing a good understanding of the underlying tensions. This way, it is possible to grasp the political context of the problem being analysed (Weible, 2007: 96).

Understanding the policy process requires knowledge of the goals and perceptions of actors "over a period when these actors are actively seeking to propagate their specific spin on events" (Sabatier, 2007:4). Policy outcome would then be interpreted as the victory of a certain belief system. These features make the subsystem concept very relevant to the study of Kenyan regulatory policy subsystem. This is because it has been co-evolving alongside the technological developments for more than a decade. It has also involved many players who may be perceived to hold diverse belief systems amenable to analysis (Chapter two). The analysis consequently enhances provision of policy recommendations or actions that are commensurate with the political problem (Weible, 2007). Despite these appealing features, it has shortcomings one being that it has not been tested widely empirically especially in a developing country context.

#### **3.4.4.2 Discourse coalitions**

This concept emanates from Hajer (1995) in his study "the politics of environmental discourse" in which he explores the dynamics in environmental policy-making. Hajer's main argument is based on the fact that the social construction of environmental problems drives developments in environmental politics. The framing of issues

consequently impacts on the behaviour, organisations, institutional arrangements and the emerging policies. This approach exemplifies the way issues are talked about regarding a certain policy area. This gives rise to relationships or discourse coalitions that reflect particular strategies or consensual paths. Discourse analysis can therefore be used to identify coalitions that gather around or interpret a particular storyline. This can further be linked to a specific social practice and policy change.

This concept can be used in understanding how the Kenyan scientists construct their views around the regulatory process, which may enhance in-depth understanding of the scientific and regulatory practice. Indeed it was applied by Harsh (2008) to investigate the role of NGOs in governance of GMOs in Kenya. However, as others have noted (cf Jasanoff, 2004c), it gives a lot of attention to language which may limit its analytical potential. Discourse analysis as a methodology was not considered in this thesis which may limit its constructive operationalisation. Secondly, as empirically shown by Boschert (2005), the concept takes beliefs, interests and values as given, elevating discourse above these factors that have been found to be key in controversial science-policy debates.

### **3.5 Empirical studies on scientific practice in new knowledge terrain**

Despite the diverse roles scientists play in science policy arenas, empirical research on their role in boundary work (or policy relevant activities meant to create scientific and social order) and how these boundaries impact on their construction of perceptions and knowledge dynamics has not been given a lot of attention. In a study involving UK scientists, Waterton *et al.* (2001) and Waterton (2005) attempted to understand in practice how contemporary scientists undertake boundary work:

*“Contemporary scientists are both experiencing, in increasing intensity, science-policy boundaries of various kinds, and have the ability to sit back and reflect on their own involvement in this boundary work.” (Waterton, 2005:436)*

Waterton (2005) observes that natural scientists undergo a pragmatic shift from contemporary science practice to Mode 2 practice. This is consistent with the argument advanced by proponents of Mode 2, but in this empirical case, there were major impacts on scientific behaviour influenced by many unreported underpinning factors. Some of the characteristics demonstrated by scientists in the articulation of boundary work include:

- a) Forging of science-policy alliances or contracts which Waterton claims shape the types of knowledge constructed through negotiations:

*“The variations in co-construction of science-policy boundary in which scientists play a part means that research questions, resulting knowledge and anticipated outputs are always calibrated together with policy questions, policy knowledge and policy understanding of what constitute acceptable outputs.”*  
(Waterton 2005: 439)

Waterton further asserts that there are other different kinds of relationships that are inevitable but somewhat “counter productive” e.g. regulators. These “non-commercial” relationships have not been given proper attention in literature in view of their impact on scientific practice.

- b) Scientists have the ability to “reframe science in such a way as to enjoy policy funding and influence” prompted by reduced funding and increased competition among scientists who target same financiers.
- c) Scientists demonstrate shifting identities (though not very conspicuous) as they try to accommodate and satisfy the different relationships. As Waterton puts it, there is inconsistency and some level of awareness in the way this identity shift is played out.

*“In describing this communication (whether with fellow scientist, policy maker or sponsor), this scientist seems to be experimenting with his own identity as a scientist as much as he is experimenting with the organism he is researching.”*  
(Waterton 2005: 442)

In addition to other impacts, these different identities present communication problems due to different expectations. She however notes that contemporary scientists are actually self-conscious of the many compromises and adaptations that they have to deal with under Mode 2 research.

The changing research practice has not been confined to natural scientists only. Recent research conducted to explore the relationship between Mode 1 and Mode 2 research terrain for social scientists in Malawi showed that, they engage in consultancies outside their disciplines, and are reflexive enough to accommodate demands of patrons usually for economic gains (Holland, 2009). Reports emanating from these consultancies largely reflect the patrons' terms of references.

These two empirical cases seem to suggest that dynamics surrounding behaviour of scientists in the changing knowledge economy is complex than explained by the commercial imperatives or "knowledge commodification" (Russell *et al.*, 2008). It has something to do with endogenous individual interests and gains, rather than the commonly assumed influence by exogenous factors like multinationals, perceived to have trade interests (Middlendorf *et al.*, 2000 cited in Magnan, 2006).

Further insights have been debated under Mode 2 innovation in an effort to capture the developments in the innovations paradigm shifts (Clark *et al.*, 2009). Recently, scholars in innovation and development studies have operationalised different features of Mode 2 in different contexts.<sup>36</sup> They have opened up different and productive ways of analysing learning, knowledge use and actors' practices from an innovation perspective.

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<sup>36</sup> See for example Chataway and Hanlin (2008) in application of knowledge-flow and capacity building through networks and partnerships in health innovations; Chataway and Smith (2006) in operationalisation of communication and partnerships concepts in health innovations; Clark *et al.* (2009) in operationalisation of Mode 2 innovation and Below Radar Innovations (BRIs) in the dynamic Asian drivers economies.

### **3.6 Biotechnology innovation in the new knowledge production landscape**

The biotechnology innovation system provides a platform for analysis of unprecedented changes in institutional infrastructure and knowledge production terrain that have confronted the scientific community in recent years. The drivers of learning and institutional and social change discussed in section 3.3.1 have been operationalised in biotechnology innovation context, and have formed a reflexive debate in this area. This section explores some of the discourses around biotechnology innovation and in particular those that relate to implementation of biosafety regulations which is the main focus of this thesis.

#### ***3.6.1 Framing of GE technology as a unique branch of science & technology***

Recent developments in life sciences advanced through recombinant DNA techniques have improved the conventional biological science in various fields like pharmaceuticals, agriculture and the environment (Paarlberg, 2001: 1-3; ICTSD report, 2007: 1-12; Kelemu *et al.*, 2003:396). As these scholarly materials seem to point out, GE technology may be perceived to be different from other sciences. They allude to the fact that it is precise involving careful, strategic and selective manipulation of genes undertaken in highly regulated laboratory setting. This precision is used by GE proponents (mainly scientists) to strengthen their positive position for GE technology. Consequently, subsequent understanding and framings about this subject are based on scientific activities undertaken in such a disciplinary based and confined research environment (Mode 1 practice as conceptualised by Gibbons *et al.*, 1994). This setting is different from a normal environment under which this science is supposed to perform for its usefulness to be realised, e.g. in the farmers' fields or in the market by consumers (Scoones, 2002:4). In view of this, it can be said that the debate has been framed from the "prospects perspective" towards solving complex technical problems, rather than the "innovative perspective" that would encompass broader economic and social issues



(Hisano, 2005). The latter, purportedly normal and ideal environment would be perceived to be socially desirable in line with Nowotny *et al.* (2001) argument.

The view that biotechnology holds a key towards addressing major challenges in agricultural production especially in developing countries has been globalised and advanced at international arenas (Hisano, 2005). FAO (2004) for instance affirms and endorses agricultural biotechnology as having “potential to address the needs of the world’s poor and the food insecure”. Others have found these discourses to be misleading and sometimes confusing the debate (cf Kelemu *et al.*, 2003; Hisano, 2005). This discourse is similar to what has been described as biotechnology determinism (cf Levidow, 2007). These debates although influencing learning and knowledge production terrain in an unprecedented way have not received critical attention in the context of how knowledge and learning impact the scientific practice and related biosafety regulatory instruments.

### ***3.6.2 Biotechnology in the evolving global knowledge economy and multiple players***

Factors that impact modern biotechnology development and deployment for economic usefulness stem from globalisation reflected in the dynamic knowledge economy (Fukuda-Parr, 2006) and dynamic technological changes (Tait *et al.*, 2006). This has come with some form of reorganisation of operations. Although sometimes not very obvious to the scientist actors themselves, the hitherto localised, discipline based boundaries and operations have slowly been disorganised (Gibbons *et al.*, 1994) and replaced by increased collaborations. This integration is evident in form of public-private research not only in developed countries (Waterton *et al.*, 2001; Waterton, 2005; Scott, 2005:12-16) but also in developing countries (Ayele, *et al.*, 2006; Odame *et al.*, 2003). Clearly there has been a revolution with different disciplines integrating in a way

that seems to portray biotechnology as a unique and different form of S & T as mentioned in the preceding section.<sup>37</sup>

One factor that has contributed to these institutional changes relates to the fact that the infrastructure and the large investments involved in biotechnology transfer are beyond the capacity of individual scientists or the public research institutes. However, these inevitable collaborations have elicited conflicts, suspicion and tension amongst proponents, opponents and governments, some seeing this as positive and others wary of potential exploitation by some who may have vested interests; an indication of varying perceptions.

Biotechnology deployment is also shaped by many other actors at both national and international levels. These include multinational corporations who own the intellectual property, farmers, research scientists, anti-globalisation and environmental NGOs (Fukuda-Parr, 2006). All these actors are perceived to have diverse interests. For instance, players dominating the GMOs arena have been linked to large corporations with business agenda or exhibiting the economic culture (Middlendorf *et al.*, 2000 cited in Magnan, 2006).

Other factors that have shaped biotechnology innovation are regulatory in nature and include trade and markets (national priorities) and rules (biosafety at national and international level and IPRs) (Fukuda-Parr, 2006). Biosafety regulation which is the heart of this thesis is discussed exhaustively in the next section.

### **3.6.3 Biosafety regulation**

Application of modern biotechnology is poised to have varying environmental concerns and therefore attracts varying perceptions related to risk and uncertainties. This being the case, its transfer and consequent realisation of economic potential must go hand-in-

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<sup>37</sup> Biotechnology science is multi-disciplinary and cuts across various disciplines like molecular biology, genetics, ecology, pathology, toxicology etc.

hand with policy and regulatory innovations. This is in an effort to balance economic gains and safety (Kameri-Mbote, 2002; ICTSD report, 2007:14-57; FAO, 2006a). Regulations therefore attain a unique importance as a boundary object (Guston, 2001) in technology governance (Braithwaite *et al.*, 2007).

Globally, several legal and non-binding instruments have been put in place to regulate environmental biosafety. Most of these legal instruments have been formulated with risk and safety (precaution) as the guiding factor (Paarlberg, 2001; Scoones, 2002). The Cartagena Protocol (CP) is an example of how risk regulation has been framed in an international context. The African Model Law adopts the same approach ([www.africa-union.org/biosafety](http://www.africa-union.org/biosafety)) and some argue that it has taken a more cautious stance than the CP (Mayet, 2000, cited in Andanda, 2006:1364). These instruments mimic characteristics of process based, product based and precautionary principle approaches described extensively in risk regulation literature (cf Tait and Levidow, 1992; Tait, 2001; Marchant, 2001; Levidow, *et al.*, 1999; Dunlop, 2000).

These approaches have been interrogated and criticised in different contexts. Murphy *et al.* (2006) for instance claim that the “precautionary principle” concept has been used to attach meaning to conflicts surrounding regulations of GMOs. Paarlberg (2001) makes similar claims when analysing the regulatory approaches in different developing countries’ contexts. He identifies among others, the promotional approach that mirrors USA permissive approach, and preventive regulation similar to the EU precautionary approach. These approaches culminate into what Tait and Levidow (1992) refer to as reactive and proactive approaches that stem from actors’ perception of risk (Chataway, 1992:210). The reactive approach is process-based and those who favour it tend to be more sceptical, while the proactive approach is product-based and those who favour it tend to argue for substantial equivalence in assessment of GMOs risk (Marchant, 2001).

This reflects a polemic, polarised and political debate based on framing of regulations from risk and uncertainty perspectives (Newell, 2002).

In line with the above arguments, regulatory debates from the African context have been rife and contested. For instance, Mugwagwa (2008) exposes several regulatory approaches adopted by the Southern African countries prompted by several factors, some of which are related to safety. He however brings out other approaches that have non-safety orientation. He alludes to the proactive approach where countries embrace biotechnology as national developmental goal (developmental approach), opportunistic approach where countries engage in policy process due to available foreign funds, and the “joining the band wagon” approach where countries engage in regulatory policy process because other countries are doing so. These approaches depart from the common risk based approaches discussed above that have an origin in USA and Europe.

The “risk approach” to regulation may be perceived to be narrow from an African perspective. This is because Africa is perceived to be confronted with chronic, poverty related challenges and cannot feed its ever-increasing populace (Kelemu *et al.*, 2003; Wafula *et al.*, 2007). Proponents of biotechnology see this as an opportunity to address some of these chronic problems by tapping on the potential benefits of GE technology (Hisano, 2005), hence the need to embrace a benefit approach to regulatory approaches (Karembu *et al.*, 2008; Paarlberg, 2001, 2008). There have been recent initiatives by the scientific community to popularize this benefit concept.<sup>38</sup>

These approaches show how contested biosafety regulation is, partly because of the global, political and economic nature associated with biotechnology discussed above. This notwithstanding, these approaches have had an implication for regulatory policy trajectories being discussed or adopted in developing countries (Newell, 2002;

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<sup>38</sup> See Appendix 9; Open Forum on Agricultural Biotechnology in Africa (OFAB) at [www.ofabafrica.org/country](http://www.ofabafrica.org/country) and the Handbook for Policy Makers (2007).

Paarlberg, 2001, 2008; Scoones, 2002). Further, apart from international regulatory approaches influences, Africa has regional and transnational bodies that are promoting certain regulatory approaches.<sup>39</sup>

Despite these contested approaches to biosafety regulation, African governments have recognised the need to embrace modern biotechnology in addressing some of the agricultural production constraints (Juma and Serageldin, 2007). Further, they have understood the nature of biotechnology as a double-edged sword; as beneficial as well as risky (related to its application). This is evidenced by the numerous motivations and initiatives to engage in development of effective regulatory mechanisms (Mugwagwa, 2008; Nang'ayo, 2007; UNEP-GEF, 1995; FAO, 2006a; AATF, 2006; Sengooba *et al.*, 2005). Most emerging frameworks aim at building biosafety institutional capacity for responsible implementation of GE activities. Actually, in Africa, it was conceived early that benefiting from modern biotechnology depended on parallel development of biosafety regulations and biosafety capacity for implementation (Mugoya *et al.*, 2002; Mugoya, 2007). It is however not clear how this parallel model of technology development alongside regulatory regime may impact regulatory practice and policy instruments, as well as the broader innovation process.

### **3.7 Chapter conclusion and summary**

A critical analysis of the foregoing literature seems to indicate that scientific practice is impacted by, not only institutional factors that are complex, but also by social and culturally embedded factors which most theoretical approaches in knowledge dynamics fail to capture vividly. The changing institutional terrain for agricultural biotechnology innovation and the unstable role of scientists in science policy boundaries suggest that scientists get entangled in the regulatory policy debates in diverse ways. Despite this,

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<sup>39</sup> EAC, AU, COMESA; see also attempts by PBS towards harmonisation of confined field standards within East Africa [Sengooba *et al.*, (2005); Linacre and Cohen (2006)] and in harmonisation of regulatory policy efforts within Africa (Mugwagwa, 2008).

role of scientists in science policy deliberations as epistemic communities on the one hand, and as innovation drivers within communities of practice on the other, continues to be valuable (Haas, 1992, 2004; Weingart, 1999; Johnson, 2007). But productive engagement is threatened by the changing linear and non linear modes of knowledge production that cause strains at individual, institutional and organisational levels. This causes confusion in terms of the way scientists and policy experts are expected to behave.

Although cultural and behavioural shifts in scientific practice related to pressure of funding has been acknowledged in boundary work (Waterton, 2005), literature has not explicitly articulated the shifts or behavioural patterns impacted upon actors by the inevitable paradigm shift from the basic research practice to the integrated practice called for by biotechnology innovation and related biosafety regulation. Overall, in a bid to deal with the difficulties that constrain learning and knowledge production, scientists turn to different integration strategies that include among others enlisting of relationships like policy coalitions. This new and integrated policy working environment is further confounded by the contentious governance issues linked to biotechnology as a new life science. Consequently, this complex scenario evokes different social identities reflected in different behavioural shifts.

Meanwhile, Table (5) below presents a summary of issues and theoretical approaches explored in this chapter, and the missing gaps that the narrative presented in subsequent chapters attempts to address.

**Table 5: Summary of literature and limitation for this research**

CHAPTER SUMMARY		
Issue	Literature	Findings/what is lacking for this research
Governance of new life sciences	This has been debated from the context of participative decision-making processes. Focus has been the overall institutional and policy change. Attention is given to evidence-based decision-making processes.	Less attention is given to articulation of multiple forms of evidence (knowledge) that should guide legitimate policy processes. This may imply that individual social actors who are knowledge producers and drivers are masked by this generalised approach.
Science and society	Changing role of science in society prompted by changing knowledge economy, environmental imperatives and informed society.	This is scattered within various bodies of literature that are complementary when analysed from knowledge perspective.
Scientific practice	Innovation systems concept explains learning and knowledge dynamics within a dynamic innovation system.	-Less attention given to learning of social actors in regulatory policy related interactions and networks. Social actors play a key role in knowledge dynamics. -There is need to understand the dynamics behind regulatory policy innovations where the context of knowledge use may be different, process short lived, relationships informal and sometimes end product is definite (e.g. development of a regulatory instrument).
	Mode 2 concept carefully explains the changing knowledge dynamics in new sciences in relation to actors' transformed practice.	-Operationalisation of contextualised practice is limited to technological research and gives less attention to policy innovations like regulations. This opens a new avenue for investigating scientific practice. -Trans-disciplinary practice somewhat different in implementation of regulations suggesting further investigation in the context of policy innovation rather than the traditional technological focus.
	Policy coalitions explain policy knowledge dynamics within networks in policy processes.	-This concept complements Mode 2 principles. -There is no empirical application of this concept in the biosafety regulatory processes. -Concept underplays certain factors like interests, influence and relationships that are identified as key in science policy and innovation systems literature.
Biosafety regulation	Most approaches to regulation are risk or promises based, that seem to situate scientist actors as having a narrow view of innovation.	-Context specific literature scanty particularly with regards to empirical studies in developing countries. -Perceptions of regulations and factors influencing these perceptions are not clear from the empirically grounded literature.

The gaps summarised in this section therefore legitimise a study that would illuminate empirically how scientists get entangled and how they navigate their way through the challenging knowledge production terrain, while upholding their scientific ethos and disciplinary identities. Such a study may be important because of the trans-disciplinary nature of biotechnology, which may imply that certain regulatory behaviour may be reinforced by different cultures colliding in this setting. It would also bring insights in the way scientists use policy relevant knowledge to impact policy change the new life sciences. In addition, the governance of biotechnology has called for new ways of doing things towards governance agenda rather than the controlled government approach (Tait *et al.*, 2006). It is again empirically unclear how governance approach to regulation, particularly at a micro or local level might affect the scientific and related regulatory practice.

Since one of the objectives of this thesis is to offer suggestions on better ways of governing biotechnology, the insights generated from this literature review, although from a global and general context inform this endeavour. But first the methodology applied to generate empirical data to support the subsequent discussion is presented in the next chapter.



## 4 Methodology

### 4.1 Introduction

This research is about the perspectives of the scientific community regarding implementation of biosafety regulations and the role of this community in shaping the regulatory process and instruments. The approach to this study assumed the existence of diverse perspectives and practices dictated by the controversies and contextual factors driving the debate in governance of the new life sciences. These aspects had a bearing on the integrated research design adopted that provided flexibility for the scientists' views to come through despite these factors. However, guided by the research questions, I had to steer clear of the controversies inherent in GMOs debate.

This chapter presents the resulting research design detailing the research methods used after introduction of two important aspects that shaped the overall methodology: firstly, my professional background that was a motivation for this study and secondly, an overview of the adopted line of enquiry. Following this, subsequent sections describe the process of data generation and analysis. It is important to point out that, the research stages were not as clear-cut as presented here. This is because the methods were iterative and evolved as data generation, analysis and writing progressed.

How the issues of researcher's bias, ethics, data validity and reliability were dealt with is also covered explicitly across the sections, against the challenges and opportunities encountered during the research process.

## 4.2 Personal background

Trained as a biological scientist, I got involved in the plant protection (quarantine) regulatory work in 1999 as a practitioner employed by Kenya Plant Health Inspectorate Service (KEPHIS). When the biotechnology activities commenced in Kenya in the 1990's, KEPHIS became the main government institution enforcing the monitoring and inspection aspects guided by the interim biosafety regulations published in 1998 (RoK, 1998). Capacity in both biotechnology and biosafety was a challenge for the government and the organisations involved. This resulted into both national and organisational collaborative efforts to build the requisite capacity. I was one of those people who benefited from this early and subsequent capacity building efforts, receiving training in modern biotechnology techniques as well as biosafety. KEPHIS later became a key player in the biosafety regulatory instruments formulation, and consequently I became actively involved as a regulator, interacting extensively with biological scientists in the biotechnology arena. This may therefore imply that I have brought, though not deliberately, my own understanding of issues influenced by my previous traditional disciplines, into the social science methodological approaches.<sup>40</sup>

Rather than assume or ignore this academic and professional background and experience, I adopted a heuristic form of enquiry, prompted by this self-reflective question:

*“What is my experience of this phenomenon and the essential experience of others who also experience this phenomenon intensely?”* (Patton, 2002: 107)

Heuristic research is not detached from researcher's personal experiences, reflections and insights. It endeavours to disclose the truth through understanding of tacit knowledge. These attributes are enhanced through its two basic principles: first, the researcher must have a personal experience with, and intense interest in the

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<sup>40</sup> This may have both advantages and disadvantages that are discussed further on in the chapter.

phenomenon under study and two, others who are part of the study (e.g. scientific community interviewees) must share an intensity of experience with the phenomenon (Patton, 2002: 107). Consequently, the eight years I worked as a regulator while interacting with the biological scientists (myself being one), prompted me to adopt an interdisciplinary approach to the research design and other methodological approaches used in this research. The purpose was generally to enhance the interpretation of the empirical data in the best way possible rather than test any existing social science theory or approach.

### **4.3 Qualitative approach**

The subjective views of the scientific community related to implementation of regulations, the reasons why they hold these perspectives and their behaviour related to regulatory process were the topic for interpretation in this study. What was important therefore was the scientists' worldview, solicited through a qualitative approach. This approach is different from the quantitative approach that adopts tests, surveys and experiments in data generation (Glatthorn, 1998: 34). Creswell (2007:3) argues that, there is no antagonism in choosing either a qualitative or quantitative approach as they represent "different ends of a continuum". However, it was understood that statistical methods could yield a lot of quantitative data, but to generate rich data embedded in the accounts of those who make regulations and those affected by these rules, a qualitative approach was found to be promising. As Silverman (2005) observes, qualitative research sacrifices scope for detail. Thus, engaging qualitative methods were used which entailed in-depth semi-structured interviews complemented with observations and documentary research.

This research is therefore "grounded" in the interpretations of the interviewees which is the ultimate aim of qualitative research - that of generating ideas or concepts that

illuminate the issues under investigation (Hammersley, *et al.*, 2001). In this study the issues being illuminated were scientists' perceptions surrounding regulations and regulatory practice. Consequently, the emerging themes are supported by examples while considering the context under which the research was carried out (Rubin and Rubin, 2005). Context was an important aspect in this research because of the different contextual circumstances involved. For example, the different interviewees' academic, professional or institutional backgrounds may imply that divergent perspectives could emerge under these different circumstances.

Because of the heuristic inquiry adopted, this research was explicitly reflexive. Most qualitative approaches exemplify the importance of reflexivity (cf Etherington, 2004; Bryman, 2004:500; Robson, 2002). Robson defines reflexivity as "awareness of the ways in which the researcher as an individual with a particular social identity and background has an impact on the research process" since s/he is not detached from the social world s/he is researching (Robson, 2002:172). This position is also shared by Gillham (2000) who asserts that it is common for researchers to carry their prior conceptualisations and prejudices into the fieldwork based on their background and experiences. Consequently, he recommends that the researcher should be conscious of this, acknowledge the prejudices upfront, and aspire to maintain an open mind. This implies that through reflexivity, a researcher is able to put aside personal preconceived ideas as well as acknowledge the preconceived perceptions related to him/her, held by the participants. This is achieved through critical reflection on the practice, the process of research and the role of the researcher (Litchman, 2006).

Adopting a reflexive and heuristic approach made me approach the data collection with an open mind, hence navigated this process reflexively (see for instance section 4.6.4 detailing how interviewing was approached). I was aware that I had some preconceived

perceptions of scientists and the Kenyan regulatory process (having been part of it for eight years), but I sought to keep these out of the research process, endeavouring instead to learn from the field.

It is important to note at this point that throughout the research process, various components co-evolved: the theoretical perspectives informing this study, the field work and data generation, and writing to eventually come up with the final thesis. The process of data collection, review and analysis continued even during the writing process. For instance, during the final stages of writing up, I continued to gather and review additional data based on identified gaps and new insights, which were integrated into the research analysis. Further, the writing process continued to be informed by controversies surrounding the biosafety bill, which intensified after the fieldwork.<sup>41</sup>

#### **4.4 Review of methods used in studies concerning perceptions and practices of scientists**

The contested context that confronts any research related to controversial technologies like biotechnology has already been mentioned elsewhere. This section looks at specific previous work related to scientists' attitudes and practice towards biotechnology innovation with a focus on subjects relevant to this study. In general, there are very few empirical studies in these areas (scientists' perceptions and practice). Some are discussed here with a view of locating the strengths and weaknesses, which informed the methods selected for this study.

Previous work has shown that scientists differ in their perceptions related to risks and biotechnology (see Chapter three, sections 3.4.3 & 3.6.3). Several reasons have been attributed to this ranging across organisational affiliations, public perception of science, political and scientific values and the different meanings attached to the framing of risk

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<sup>41</sup> The biosafety bill development process continued to receive a lot of attention from the public front even after fieldwork (see Appendices 7 & 9).

and benefits of GE science. The methods applied in these empirical studies have ranged from questionnaires and surveys (Lynn, 1986; Rabino, 1991, 1994), as well as interviews (Lynn, 1986; Scott, 2005; Cohen *et al.*, 2001; Harsh, 2008). It is not very clear though how the methods adopted in these studies could have influenced the reported findings. However, in depth interviewing has been proved to be a useful instrument in the study of scientists' belief systems when compared to the other methods due to its ability to elicit detailed views of interviewees (Scott, 2005).

Regarding scientific practice, very few empirical studies have been conducted in this regard. Some relate to scientists' experiences as they adapt to new working environments demanded by the new sciences as well as the changing research-funding scenario (Waterton, 2001, 2005; Cohen *et al.*, 2001). Both these studies involved UK scientists but no such research has been conducted in the African context. Even more important but neglected aspect is the scientists' practice in the regulatory policy-making. From the Kenyan context, Harsh (2008) through interviews demonstrates how and why NGOs scientists get entangled in the politics of biotechnology and biosafety policy-making.

Even with inadequate empirical studies on this subject (scientists' perceptions and practice), it is now clear that developing countries have limiting contextual issues like the relative different roles of actors and institutions (government and non government) that drive biotechnology policy processes (Harsh, 2009; Mugwagwa, 2009; Smith, 2009; Newell, 2002; Scoones, 2002). Despite this knowledge, it is not clear how these contextual issues may be factored into the methodology. This notwithstanding, the empirical studies reported here used interviews, which yielded important data related to perceptions and practice of actors. Consequently, the in-depth, semi-structured interviewing (among other methods) was considered to be an important method for

studying the perceptions and practice of Kenyan scientists related to the biosafety regulations and implementation.

#### **4.5 The context of the study**

The preceding sections outlined the basic approaches that informed the research design and the line of enquiry and in so doing tried to locate this research in the broad qualitative research approaches. The personal background reinforced these approaches thus justifying the interdisciplinary and integrated approach adopted in this study. This section describes the process of data generation starting with the rationale for selection of the study context. This is followed by the methods employed to generate these data.

##### ***4.5.1 Choice of the study context***

To generate rich data pertaining to scientific community's real experiences in the implementation of regulations related to biotechnology as a new science, there was need to target a setting that would enhance this. Maxwell (2005) emphasises the importance of focusing on aspects that are data rich in qualitative research. The "biosafety regulations implementation" was perceived to be an invaluable process through which rich data could be generated. In addition, it was important to select participants who had a stake in this process. Based on this, the rationale for selecting Kenya as a study area and biological scientists as main participants was based on several factors:

- i. There is a significant body of literature on the Kenyan regulatory policy process that informed the problem statement. This literature reveals that the establishment of the Kenyan biosafety regulatory regime had become controversial (Sander, 2007; Harsh, 2005, 2008).
- ii. Prior to and during the field work, the selected participants were actively engaged in this process in various ways (pilot study undertaken in Dec 2006 to Jan 2007; mass media reportage).

- iii. Kenya is perceived to have advanced both in terms of GE research and development (R & D), and progress made towards establishment of a biosafety regulatory regime (Nang'ayo, 2007). This factor further strengthened the rationale for preferring scientific community because at the period of this study, no GE product had gone beyond research stage implying that the other stakeholders (like farmers or consumers) had marginally been involved in its deployment.
- iv. Kenya is host to many non-state organisations (NGOs) perceived to be pro-biotechnology (Harsh, 2005, 2008; Sander, 2007). This factor made it possible to further expand the scope of interviewees to include scientists from NGOs.
- v. Familiarity with the research terrain (see section 4.2) was perceived to be an advantage in terms of access.

Having selected Kenya as the study area (and biological scientists chosen as main participants discussed further below), the fieldwork was carried out from 1<sup>st</sup> October 2007 to 15<sup>th</sup> April 2008.

It is important to report that the fieldwork coincided with the general elections in late 2007 and there were incidents of extreme political skirmishes, sparked by disputed elections results. This caused a minimum delay in the data generation process.

#### ***4.5.2 Participants selection***

This study relates to how the scientific community view the biosafety regulations implementation and how they behave or react towards this process. In this regard, representativeness was paramount [the representativeness of the process (biosafety regulations implementation) and of individuals likely to be articulating or heavily involved in this process at that particular point in time (R & D stage of biotechnology



activities and the formulation of biosafety regulatory instruments)]. Consequently, selective sampling was preferred (Maxwell, 2005) since random sampling would not have acquired this objective. For instance, only a small proportion of academic, policy and NGOs scientists are involved in GE research and biosafety regulatory work. In addition, heterogeneity within the scientific community as well as establishment of possible comparisons or divergences amongst them was important.

Interviewees were therefore purposefully selected ranging across practitioners, policy makers, academics and civil society. Snowball sampling also happened later during fieldwork after previous interviewees recommended other participants. In addition, the fieldwork coincided with a period when the public was debating the biosafety bill. Thus, statements issued through media provided a link to interviewees who seemed to be opposing the process. Consequently a total of 42 participants, who have been involved in biotechnology research and biosafety policy-making in their various capacities as biological scientists and as non-scientists were selected (Table 6). They were also affiliated to organisations that have (or claim to have) a stake in modern biotechnology and biosafety arena. They include key senior officials in the NGOs circles, public research and academic institutions, regulatory organisations and government ministries, and biotechnology R & D coordinators and principle investigators (see Appendix I for the detailed list that captures the institutional affiliations and professional backgrounds).

**Table 6: Research participants**

	Categories of participants	Participant code	Institutes/org	No.
1	GE Practitioners (GP) are (or have previously) engaged in GE activities. Some in the interviews claimed to be passionate about GE work. The professional profile information supports this claim as well as institutional documents.	RSPu-GP1, RSIn-GP2, RSIn-GP3, RSPu-GP4, RSAc-GP5, RSPo-GP6, RSPu-GP7, RSPu-GP8, RSIn-GP9	Public research, public universities and international organisations.	9
2	Policy Scientists (PS) are either senior government officials, biological scientists in the NBC and/or IBC and regulatory institutions. The senior government officers are (or have been heads of government institutions or ministries). The scientists in the NBC and IBC are generally from public academic institutions, regulatory agencies and one international research organisation. Some of them are affiliated to other professionally related institutions. Participants in this group are all connected to GE research in one way or another.	Blp-PS1, ARp-PS2, ATp-PS3, PRp-PS4, ATBp-PS5, RSIn-PS6, RSPu-PS7, RSPu-PS8, ARp-PS9, PRp-PS10, Blp-PS11, FSp-PS12, Blp-PS13, ABp-PS14, ENp-PS15, ARBp-PS16	Government ministries, public universities, international research institutes, regulatory agencies and public universities.	16
3	Non State Scientists (NSS or NGOs) belong to non-governmental organisations with a stake in biotechnology activities. They are backed up by their biological science background.	TAR-NSS1, TAN-NSS2, TRTp-NSS3, TAN-NSS4, EPA-NSS5, TAD-NSS6	International & regional organisations, NGOs & donor agencies.	6
4	Non-Biologists Scientists & Non-Scientists (NS). Participants in this category are spread out in civil society, lawyers, journalists, biotechnology industry and funding organisations and include social scientists.	NGOf-NS1, NGOf-NS2, NGOcs-NS3, NGOco-NS4, NGOco-NS5, JO-NS6, JO-NS7, LABp-NS8, LAEp-NS9, TAI-NS10, TAD-NS11	Government legal arm, civil society, farmers & consumer associations, media, industry and donor agency.	11
<b>Total</b>				<b>42</b>

By and large, prior interaction with majority of the participants facilitated access to individual interviewees and detailed information about the scientists and their working environment. Maxwell (2005) argues that this sort of familiarity with research environment may be both advantageous and disadvantageous to any qualitative research. I acknowledged early at the design of the project that this prior relationship with participants could have a negative impact on the research findings, resulting in critical reflection, while paying attention to the potential “researcher’s bias” or “interviewees’ reactivity” that could have affected the reliability of the findings (Maxwell, 2005:108-109). Maxwell further notes that this reflection and resultant

flexibility can be productive since emerging insights can be used to revise research design or generate different types of data (*Ibid*:81).

This study required me on the one hand to have a unique relationship with the participants, different from the regulator-scientist “policing” relationship. On the other hand it required me to understand the perspectives of the participants without bias, as well as encourage an environment that would enhance trust and minimise suspicion. This was accomplished through; one, explaining the purpose of the research; and two, establishing a “researcher-respondent partner” kind of relationship (Maxwell, 2005). I emphasized that it was important for them as respondents to be candid about their experiences as co-partners in this research study (see section 4.2). In addition, triangulation enhanced validity of research process and findings as discussed next.

#### **4.6 Data generation and triangulation**

This study focused on both the perspectives and behaviour of interviewees related to regulations implementation. The “what” “why” “how” and the “so what” nature of the three research questions had to be tackled (Chapter one, section 1.2.1). Subsequent methods were therefore selected based on this. In view of this, the research approach considered a variety of sources and methods, endeavouring to gain broader and more secure insights of the participants and their experiences as well as experiences of others in the biotechnology and biosafety arena. It was important therefore to adopt methods that could allow views of participants to come through explicitly by applying triangulation in form of both data generation instruments and data sources. According to Denzin and Lincoln (2005), triangulation adds rigour, breadth, complexity, richness and depth to an inquiry. In this study, different methods and instruments were applied to reveal diversities and similarities in perceptions hence increasing trustworthiness and enhancing in-depth understanding of perspectives of participants.

#### **4.6.1 Data generation**

Various sources of data were used (three categories of scientists; non scientists; field notes). The four categories of participants therefore enhanced validation of accounts across these groups in order to expose areas of agreements and disagreements. Field notes were captured through informal and formal gatherings, informal observations and casual conversations, organisational documents, mass media reportage, policy documents, correspondences between ministries and government departments, and statements from policy makers.

In addition, the data were also collected using **multiple data generation instruments**. For instance, data from participants was collected through formal interviewing alongside other informal activities that included, attending scientific and policy fora, reviewing scientific and policy related publications, and review of presentations made by scientists and policy makers during various local conferences. By participating in formal and informal gatherings organised by the scientific community, I engaged in casual conversations and sometimes incidental observations. This way, I made descriptive field notes that provided crucial contextual information.

Multiple methods and multiple sources of data further enhanced credibility and accuracy of the findings, minimising potential limitations likely to emerge while using one method (Maxwell, 2005:94).

#### **4.6.2 Observations**

Formal or informal observations offer a direct contact with the participants and the settings in which the research is being undertaken (Patton, 2002). Patton further argues that this has various advantages ranging from encounter with the real setting, understanding the order of interactions, noticing the taken for granted things, learning things that are concealed during interviews, and the researcher forming personal

impressions that enhance reflection during the data analysis (*Ibid.*:261-264). Hammersley and Atkinson (2007) further reinforce this argument by noting that even studies that use interviews as the main method still employ observational methods to note the body language and other gestures that are consequently linked to what the interviewee is saying. Further as Angrosino observes, observation in social science is perceived to be “a convincing form of verification” (Angrosino, 2005:730).

There are different types of observations. Yin (2003) for instance talks of direct and formal observation. Although in a formal observation (or participant observation),<sup>42</sup> one is expected to have a long-term involvement with the participant, this study concentrated on direct observation during a fieldwork period that lasted about six months. Thus, the direct observation involved focussing on specific activities undertaken by the scientific community related to the regulatory process.

I participated in several biotechnology and biosafety fora and institutional meetings that I was invited to attend.<sup>43</sup> This opened up opportunities for observing the participants face to face and in their active environment (practice). Consequently, I made notes of the undertakings related to; who, when, and where, including the context under which a particular behaviour was being exhibited (Angrosino, 2005). For instance, a breakfast meeting I attended involving pro-biotechnology NGOs scientists, policy scientists, industry and practising scientists (most happened to be target participants) discussed rhetorical strategies that could be adopted in engaging the government and the parliamentarians towards the enactment of the controversial biosafety bill.

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<sup>42</sup> Although this is discussed in the context of case studies, Yin (2003:86, 92-96) gives a distinction between direct observation and participant observation. For the former, opportunities for observation tend to be informal as one visits the “site” while in the latter case, the researcher assumes an active role within the case being studied. Both have strengths related to “covering reality in real time” and are “contextual.”

<sup>43</sup> For instance, Codex meeting on labelling of GMOs on 15 Nov. 2007 at KEBS headquarters, Nairobi; Various OFAB meetings between Oct, 2007 & Mar, 2008, in Nairobi; Biotechnology/Biosafety Consortium Meeting of 5 Dec. 2007 held at MOA headquarters, Nairobi; Biotechnology/Biosafety Consortium meeting of 3 Apr. 2008 organised by ABSF at Panafric Hotel; KEPHIS & KEBS GMOs meeting on 22 Nov. 2007 at KEBS headquarters, Nairobi.

Consequently, personal observations captured how the scientific community engage in negotiations related to policies that are of interest to them, their motivations as well as gaining of understanding about the practical Kenyan biosafety legislative process. Differences between the different groups of participants were noted in a way that could be linked to previous or subsequent interviews involving some of them. Sometimes subsequent interview questions were guided by the impressions and information obtained from prior observations. Permission to be part of these fora was a good sign that the participants had no suspicion related to my being present.

Direct observations were also undertaken during interviews, basically paying attention to the details of the interview setting and consequently recording this. This was actually provided for in the interview guide (see Part 1 of Appendix 2).

Patton (2002: 274) notes that the duration of observations largely depends on the time and resources available to the researcher. Time was a limiting factor in this study and therefore actual, long term participant observation could not be achieved. This was further complicated by the fact that all the participants were spread out across different organisations, thus difficult to get one suitable case study representing the different categories of scientists.

#### **4.6.3 Documents**

Documents are important sources of data (Bryman, 2004:381-397). Yin (2003:86-87) argues that documents can be used to validate and complement evidence from other sources. In this study, various documents were used at various levels, either before fieldwork, during field work or after fieldwork. They augmented observations and interview data with regards to the dynamics of biotechnology and biosafety process in Kenya. The documents were bringing out interesting insights related to the behaviour of

scientists, their role and other actors' role in the regulatory process. They were therefore serving the complementary, validation and corroboration purposes.

This research is also about implementation of biosafety regulations. In view of this, several documents that charter and direct this process through the guidance they give to policy targets, policy makers and regulators were extensively consulted and reviewed. These include: the regulations and guidelines of 1998 & 2003, the biosafety bill, 2008 including a counter parallel bill (the biotechnology and biosafety bill, 2008) originating from the civil society, the biotechnology policy, 2006, the manual for inspection and monitoring of GMOs in Kenya, the draft regulations for conduct of field trials among other policy instruments (see Table 8 & section 5.2 in Chapter five). Other documents included media reports (see Appendix 9 for a summary of key reports), other relevant Acts of parliament like EMCA Act, 1999, official reports and proceedings of government and public deliberations, correspondences between institutions, publicly available scientific reports or testimonies, parliamentary debates on biosafety bill, organisations or government departments brochures, newsletters and profiles. Some of these reports are available from various websites while others were obtained during fieldwork from various sources including the participants themselves. Caution was taken to establish confidentiality status in order to guide their subsequent use.

Emphasis was given to the quality of the documents in order to address the issue of credibility and potential bias related to the source (Bryman, 2004). The issue of authenticity was taken seriously and during the interviews, certain documentary evidence was discussed with key participants as a way of validation. However, it was understood that documents would not provide objective accounts of the status quo and therefore they were analysed in the context of other sources of data.

#### **4.6.4 Interviews**

Interviews were conducted in Nairobi, and a few in the outskirts of Nairobi between October 2007 and March 2008. The fieldwork coincided with a period when the biosafety bill was being debated in parliament and there were increased media reports from both the anti and pro groups related to the bill and its formulation process (see Appendix 9). This became a key subject that was passionately discussed by all participants during the interviews.

##### **4.6.4.1 Ethical considerations**

Prior to fieldwork, the Open University Ethics committee approved this research.<sup>44</sup> It also received approval from the Ministry of Education, Science and Technology in Nairobi, Kenya.<sup>45</sup> The first approval required that interviewees consented to being interviewed and recorded in addition to making the purpose of the research known prior to the interviews. Participants were provided with the option to withdraw at any point in the interview process or to decline to comment. This was provided for in the consent forms and letters of introduction sent to them prior to the fieldwork (see Appendix 3).

All the interviews consented to being interviewed and being recorded, however, only 37 signed the consent form. In the consent form there was a provision for anonymity. Most interviewees preferred their identity to be concealed during report writing, unless where they would be given an opportunity to approve the content before hand. Some categorically expressed their wish to have the organisations they worked for not linked to their expressed views. A few interviewees requested either the audio recorder to be switched off at some point, expressing their wish to have certain opinions not being made public. In reporting the findings, the identity of the interviewees has been kept confidential but I cannot eliminate the risk of forming an opinion about the interviewees

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<sup>44</sup> Ethical approval reference HPMEC/07/#339/1 dated 26 Sep. 2007.

<sup>45</sup> Research Permit No. MoEST13/001/37C 728 dated 26 Oct. 2007.



as a result of the findings (partly because of my previous professional status as a regulator).

#### **4.6.4.2 Interviewing process**

Interviews are of many types ranging from structured, semi-structured and open-ended (Rubin and Rubin, 2005). They may also take the form of face-to-face verbal exchanges or one-to-one telephone conversations. One-to-one, in-depth semi-structured interview approach was employed in this study. As some authors have noted, in-depth interview provide a flexible and adaptive approach to situations and context of participants, checking against the researcher's pre-conceived biased ideas (Gubrium and Holstein, 2001; Rubin and Rubin, 2005; Robson, 2002). This strength differentiates in-depth interviews from other data generation methods. This has many advantages that include increased reliability and validity. Semi-structured interviews begin with a pre-determined set of questions, but allowing flexibility as interviewing progresses.

A theoretically informed interview guide was prepared prior to the fieldwork, tailored to each group of participants (GE practitioners, scientists in the policy & regulatory arena, NGOs and biotechnology industry, and the civil society). This interview guide as much as possible captured the main thematic areas surrounding the biosafety implementation process. These thematic areas included (and not limited to) perceptions of the following: GE technology, regulatory policy and approval process, biosafety risk related to field trials, scientists' role in the policy process and stakeholders' engagement in the policy process (see details in Appendix 2; part 2). Adjusting of the themes was possible because of the semi-structured nature of the questions (Rubin and Rubin, 2005:129-151). Consequently, the interview guide was later adjusted reflexively to accommodate each individual, after adequate information related to them or their affiliated organisations was gathered.

Forty-two participants were involved in this study. Consequently, forty-two interviews were conducted at venues that interviewees found convenient that ranged from offices, restaurants and in one case, inside the car. They were all recorded using a digital audio recorder. During the interviews, flexibility was enhanced through allowing the interviewee to guide the process in what Gubrium and Holstein (2001:111) describe as “moving with the flow” which permits eliciting of productive and sometimes unexpected information. I only came in to confine the process to the anticipated scope to avoid potential deviation from the study focus.

The interview guide provided the guidance needed, but follow-up questions and probes were asked. Follow-up questions were guided by comments made by the interviewee while probes were to request for clarifications or emphasis of what was said regarding a particular issue. This enhances “depth, detail, vividness, richness and nuance” (Rubin and Rubin, 2005:129). As Rubin and Rubin further assert, interviewing skills are very important in achieving this depth. The pilot study conducted in Dec 2006 to Jan 2007 was essential and enhanced the interviewing techniques applied in this study.

Interview sessions lasted between 30 minutes to two hours mainly based on the interviewees’ availability.<sup>46</sup> Prior to the interview or immediately after each interview, observational notes were made, detailing the interview setting.<sup>47</sup>

To further enhance reliability and credibility of each account, prior to each interview session, it was made very clear that the research was being undertaken as part of a doctoral project and that it had nothing to do with KEPHIS. This was to reinforce the emphasis made in the invitation/information letters (see Appendix 3, third letter) sent to interviewees prior to fieldwork.

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<sup>46</sup> Interviews with the GE practitioners and policy scientists took longer than the interviews with the other groups of interviewees. This is because there were practice-related questions that were pertinent only to them. By and large, the questions tried to elucidate the perceptions of the interviewees regarding the interview themes.

<sup>47</sup> The notes included the perceived response and reaction to the questions where appropriate.

Although this resulted into relaxation, some interviewees had a lot of expectation from this research. This is because majority of the pro-biotechnology scientists have been critical of the regulatory process (revealed through literature and pilot study) and therefore welcomed the study with a hope of the findings informing and consequently impacting the process in terms of efficiency. One interviewee who plans to put up an application for GE sorghum remarked:

*“We want you to evolve [change] in terms of regulating us [those interested in GE research in Kenya].....please I will ask you to advise KEPHIS to please build the regulatory capacity for sorghum.”* (TAR-NSS1, researcher & technology advocacy, international NGO, Feb. 2008)

Despite the measures taken to enhance reliability, assumptions were not made regarding any potential bias. As Robson (2002:173) notes, even if biases are acknowledged, they are culturally embedded and may not be done away with easily. In view of this, this research gave careful attention to the data generation, triangulation and analysis process. In this regard, my being a biological scientist and having been a regulator as well as having interacted with interviewees previously, was therefore not a validity threat to findings and conclusions of this thesis.

#### **4.7 Data analysis**

This far the chapter has described the general methodological approaches and how particular methods were selected and operationalised to eventually generate the data. This section now turns to the process of data analysis, discussed in details to demonstrate how this study is grounded in the participants' accounts of their worldview (inductive).

The data analysis adopted a thematic approach. As Braun and Clarke (2006) observe, thematic analysis is a method of identifying, analysing and reporting patterns within data. Fereday and Muir-Cochrane (2006: 4) hold similar views, arguing that it involves

“careful reading and re-reading of the data, a form of pattern recognition within the data where emerging themes become the categories for analysis”. This process is described and elaborated further below in section 4.7.2.

Cognitive mapping was also used as a data organisation and analysis tool thereby presenting the views and actions of participants in a form that is amenable to analysis for potential implications related to practice and possible policy recommendations.

#### ***4.7.1 Deductive and inductive process***

The literature review prior to fieldwork and the prior knowledge of the study context enhanced the development of a theoretical framework and scope for this study that comprised of particular objectives and research questions (see Chapter one). In other words, this framework provided a boundary within which the data generation and analysis was confined. It can therefore be said that this initial literature and the context-led framework building adopted a deductive process. Further, insights that informed the conceptualisation of data during fieldwork constituted the beginning of data analysis and formed part of the record of field experience (Patton, 2002: 436). For instance, all the interviews were concluded with an analytical section referred to as “observational notes” that described the interview setting. This implies that data analysis commenced early, adopting an iterative practice with early decisions being informed by the research design, while the later analysis stages consequently being informed by data (Maxwell, 2005: 95).

As illustrated further below, coding adopted both inductive and deductive approach. Indeed, the entire data analysis process was both deductive and inductive as recommended by some scholars who favour this approach. Patton (2002: 437) for instance suggests that analysis should be guided by research question on the one hand and insights and interpretations that emerge during data collection on the other. Foss

and Waters (2007) also recommend a similar approach, but they caution against interpretation of the approach as theory-led as opposed to a way of organising the data analysis process.

#### **4.7.2 *Thematic coding***

All the audio recorded interviews and conversations were transcribed verbatim. The field notes and selected documents were re-read and organised such that sections of text concerning themes of interest related to implementation of biosafety regulations and practices of scientists were identified. At the early point of listening to the recorded interviews with the help of the digital voice editor 2, and the reading and re-reading of the notes or transcripts, notes were made for future reference in later data analyses. These notes consisted of early thoughts of what the data was revealing. These early activities signalled the commencement of the thematic analysis by reading and listing the patterns from transcribed data and the texts from field notes or documents.

Because the data generated were large, I devised a way of coding, bearing in mind that the objective was to organise the data in a form that is amenable to categorisation based on commonalities, differences or relationships (Patton, 2002). This was achieved through the help of the NVivo 8 software.<sup>48</sup> Transcripts from interviews and texts from documents and field notes were entered as “sources” in the internals of this programme. These “sources” aided in the initial organization and management of the data based on the different groups of participants (organizational categories). With the data coded and refined based on participants categories (see Appendix 4), the 1<sup>st</sup> level (open) coding was inductively undertaken, guided by issues that participants were critical about and why. These were closely linked to the units of analysis derived from the research questions (e.g. perceptions of regulations). Various distinct categories (or labels) were

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<sup>48</sup> NVivo 8 (2007) provided by QSR International apart from aiding in data organisation also facilitated retrieval and easy access to the large data coded from all the sources. With this software it was possible to play around with excerpts by importing or merging, based on commonalities or disparities.

identified from this open coding and because they were very many, further revision of the first framework was done leading to merging of categories/labels based on the descriptions that unified them. Consequently, the labels given to specific codes reflected the characteristics they shared. This approach is similar to that described by Foss and Waters (2007: 185-215).

Further coalescing of the labels was done using insights drawn from Patton (2002:439), who emphasises the importance of “processes” as an organising principle. This study is about processes; “*implementing regulations*”, so processes became a data organizing principle. Through this approach, processes-related themes were generated. For instance, the label/category that organised codes that described “policy process and implementation” revealed processes like “*participating or engaging in the policy process*.” From these processes-related themes, a 2<sup>nd</sup> level advanced coding resulted into data-led themes following the thematic coding approach applied by Fereday and Muir-Cochrane (2006). This advanced coding generated sub-themes that succinctly described the scientists’ perceptions, revealing the issues they were concerned about regarding implementation of biosafety regulations, and reflected the language used by interviewees. At this stage, it was possible to establish commonalities or shared perspectives as well as relationships and linkages between the codes, labels and categories; both within and across interviewees’ groups. This enhanced further generation of main themes that formed the basis for data presentation. Appendix 4 is an illustration of how this interconnection was achieved using only one sub-theme (perceptions of regulations) as an example.

Although the categories identified in the first level open coding were critical in subsequent analysis, care was taken to ensure that the coding process continued to be guided by data. This being the case, constant reference was made to the raw data, the

excerpts attached to these labels and at times re-listening to selected interviews. Excerpts from data that clearly explained the meaning behind the main themes were recorded and used in creating an explanatory schema guided by insights from Foss and Waters (2007: 196-215).

### **4.7.3 Cognitive mapping**

Cognitive mapping technique was used in a limited way as an additional analytical tool to achieve two aims. One, in generating visual aids (maps) thus illustrating commonalities and differences on how ideas (concepts) were interpreted by the scientific community. Two, it facilitated the establishment of relationships (visual) between scientists' perspectives about the regulatory process and practice. The concepts obtained from coding of the empirical data were used to visually display how participants interpreted different regulatory issues and the actions they took towards dealing with them. The Decision Explorer software<sup>49</sup> aided the generation of the maps (see the generated maps in Chapter six, section 6.4).

Cognitive mapping describes the method of representing ideas as well as relationships between them in a visual form and the process can be applied to individuals as well as groups (Huff, 1990 cited in Scott, 2005). This concept originated from Kelly's theory of personal construct, which argues that "we make sense of the world in order to predict how the world will be in the future, and to decide how we might act or intervene in order to achieve what we prefer within that world" (Kelly, 1955 cited in Eden and Ackermann, 2004:616). This implies that the individual actors, inspired by their belief systems, expertise and values can take control in the way they perceive, construct, or make decisions about what kind of action to take regarding a particular problem (Swan, 1997:185). Consequently the way individuals think about a particular issue is the focus

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<sup>49</sup> This tool enhances management of the maps associated with complexity of handling many concepts (see [www.banxia.com](http://www.banxia.com)).

of the mapping techniques and can be achieved through interviews or analysis of documents (Eden and Ackermann, 2004:616).

According to Eden (2004), the visual maps generated through this technique represent the subjective world of the actors and because they are amenable to analysis, they have a policy orientation. This means that they can inform further work on the problem at hand since they are not only visual diagrams of the actors' description of their worldview, but "interpretations of what is meant by the interviewee" (Eden, 2004:675). Eden and Ackermann (2004) further reinforce this policy analysis claim, arguing that it is possible to pose the question "so what" which can result to possible policy options and in turn, devise or suggest strategies for addressing these policy options. What is not immediately clear from the visual maps generated in this study is whether the actions the participants took are positive or negative for the overall goal (moving GE technology forward from research stage to products). It is however possible to pursue the implications of their action towards policy recommendations in the light of controversies linked to GE technology (see Chapter eight).

Although this technique is popular in management research, use of cognitive mapping tool in this study was inspired by work of other researchers in the field of technology innovations. Swan (1997) applied the tool to demonstrate importance of cognitions in decisions about technological innovation in information technology. Through this tool, the nature of an innovation process in relation to knowledge structuring and decision-making could be established. She emphasises that a distinction ought to be made between cognitive maps and the output of cognitive mapping technique. The latter "describes a set of techniques that are used to try and identify subjective beliefs and to portray these externally" while the former is the outcome of the mapping technique (Fiol and Huff, 1992 cited in Swan, 1997). Levidow *et al.* (1999) applied the tool to



reveal cognitive elements from interviews undertaken with people involved in GM regulation in Britain. Chataway (1992) and Chataway and Tait (1993) applied the technique for data collection, analysis and presentation in a study looking at managers' strategic options in management of biotechnology firms. Scott (2005) used the technique to analyse the contrasting views of UK scientists regarding GM debate.

#### **4.8 Validation and reflections during data generation and analysis**

The previous sections have covered explicitly all the methodological aspects related to data generation and analysis. However, there are clear challenges that confront this type of research. These include issues of validity, reliability and generalisation of data. These challenges were tackled in various ways but the objective was to enhance credibility of the research findings. This section summarises certain issues that I reflexively reflected on, related to the data generation and analysis process in the context under which this research was being undertaken.

As interview process proceeded, adjustments were made to enhance capturing of emerging issues in the subsequent interviews. The interview guide was previously tailored to each category of interviewees based on their affiliate organisations (or employer) and background information obtained beforehand. This was found unsustainable and was revised as interviews progressed. Gubrium and Holstein (2001:113) argue that deviation from the original research plan is an important attribute of a skilled interviewer and it reveals new information that may have been taken for granted. The final categorisation of interviewees presented in Appendix 1 was therefore shaped by the progressive outcome of the data.<sup>50</sup>

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<sup>50</sup> See for example RSIIn-GP9 working for an international NGO and fitted earlier as an NGO scientist but regards himself as a GP practitioner and responded to questions as a researcher. ARBp-PS16 who was initially categorised as GP scientist for being an active plant breeder responded to questions as a policy scientist, backed by her position as a member of both an IBC and the NBC.

The overall objective of this study was to generate a portrait of the regulatory policy process and the role of scientists from the perspectives and accounts of the scientific community. The meanings they attach to the process and the ensuing action may seem as given, but trying to make a connection between the views and action is difficult. This is because there are contextual factors that were at the heart of data interpretation process. For instance, we cannot rule out the influence of the organisations that the participants work for, on opinions they expressed. Mostly, the interviewees made explicit the distinctions between their views and those of their respective employers. So it became important to cross-reference their views with the mandates of the organisations they worked for. To further ground this research in the interviewees' worldview, the in-depth semi-structured interviewing combined with observations, documentary research and validation from selected non-scientists enhanced reliable conclusions on the nature of the regulatory process and the role of the scientific community in this process.

As would be expected, there were methodological limitations linked to time constraint. For instance, validation of research process by having other players (e.g. other researchers and participants) commenting on the themes or visual maps emanating from the data was not done. However to ensure that the interviewees were aware of interpretations emanating from analysis of data, three presentations were made at conferences in Kenya which allowed opportunities for further comments by the scientific community.<sup>51</sup> Other data dissemination channels are being explored.

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<sup>51</sup> □ *Agricultural biotechnology Innovations Policy in Kenya*. KARI Biennial Science Conference and 3<sup>rd</sup> Agricultural Forum: "demand-driven agricultural technologies for sustained production", 10-14 Nov. 2008, Nairobi, Kenya.

□ *Towards a smart regulation: the case of Kenya*. 1<sup>st</sup> All African Congress on Biotechnology; Harnessing the Potential for Biotechnology for Food Security and Social-Economic Development in Africa", 22-26 Sep. 2008, Nairobi, Kenya.

□ *Can horticultural scientists do things differently in the changing knowledge production terrain? Lessons from biotechnology innovation system*. 1<sup>st</sup> all Africa horticulture congress "grown under the sun", 31 Aug. - 3 Sep. 2009, Nairobi, Kenya.

Overall, the contextual issues underpinning the aspects of this study (biosafety regulatory process and the scientific community as knowledge and innovation communities) therefore called for a reflexive and interdisciplinary research approach. Care was exercised as described in the chapter to ensure that the methodology meets the accepted rigor and credibility expected of this kind of qualitative research.

#### **4.9 Concluding remarks: linking data to theory**

The preceding sections discussed in detail the process of data generation and preliminary analysis. This early process enhanced presentation of an explanatory schema, which is the substantive subject of the chapters that follow. However, data analysis is incomplete until data is situated in the appropriate more abstract theoretical disciplines relative to the study's research questions (Bryman, 2004:497). Theoretical insights discussed explicitly in Chapter three have largely contributed to the emerging storyline presented in the next theory-building chapters of the thesis.

Meanwhile, Table (7) below presents a summary of methodology adopted in this thesis to study perspectives and practices of the scientific community in Kenya related to the implementation of biosafety regulations. It summarises insights drawn from literature and their limitations for this research.

**Table 7: Summary of previous knowledge insights and their limitation for this research**

CHAPTER SUMMARY		
Issue	Previous knowledge input for this study	Limitations for this research
Previous knowledge	<ul style="list-style-type: none"><li>-There are limited empirical studies on scientists’ belief systems and regulatory practice in agricultural biotechnology sector.</li><li>-A wide body of literature in science &amp; technology studies and governance of new sciences provided early insights and lessons that shaped the research process.</li></ul>	<ul style="list-style-type: none"><li>-Available cases expose methodological challenges in that they have used survey, questionnaires and interviews methods for data generation in an implicit way (not collectively).</li><li>-These studies are not specific to regulatory policy-making hence limited knowledge on best and appropriate methods.</li><li>-They are also not clear on how controversies in biotechnology regulatory policy process impact methodology.</li></ul>
Methodological approaches	Qualitative, reflexivity and heuristic concepts useful in qualitative research.	-To operationalise these concepts encouraged interdisciplinary approach which presented challenges. Thus, to remain focussed, only basic and few features in qualitative approaches were used.
Methods & sources of data	Multiple methods of data collection (e.g. in-depth interviews, documents and observations) & multiple sources of data (e.g. scientists, non-scientists and field notes) increase reliability and validity of data based on their strengths.	<ul style="list-style-type: none"><li>-None stand out alone to be able to withstand validity, reliability and generalisability.</li><li>-This thesis required a principled mixture of many methods.</li></ul>
		Large data were obtained from secondary interviewees (non scientists) that mainly served a validation purpose.
Data generation	This process requires skills and careful planning.	The process was influenced by unplanned prevailing circumstances and previous plans had to be re-adjusted. For example, the biosafety bill was being discussed then, which became a key theme in the analysis thus perhaps masking other regulatory themes.
Data analysis	<ul style="list-style-type: none"><li>-Deductive and inductive thematic analysis enhances a focused and data led process.</li><li>-Computer assisted coding helps in data management and organisation.</li></ul>	<ul style="list-style-type: none"><li>-Large data were generated resulting into time consuming and data management challenges.</li><li>-Thematic coding is a rigorous process and there was a limit to the use of the NVivo software. Consequently, merging of categories was done manually for the process to remain manageable, focused and productive.</li></ul>

The limitations exposed in this table and how they were tackled are factored in the entire thesis. To commence the journey involving the blending of empirical data and theory, the chapters that follow take us to the presentation of results obtained through the methods and knowledge described in this chapter.

### 5 Perspectives of Scientists on Regulations and Regulatory Practice

#### 5.1 Introduction

This chapter presents the research findings that address the first research question: *the perspectives of scientists about regulations implementation and explanations supporting these views*. The chapter is organised around the dominant themes that emerged from data coding and analysis. It is structured as follows: Firstly, the main regulatory instruments used as a benchmark in this thesis are reviewed. Following this, views regarding the nature of regulations are explored. Thirdly, the identified approaches to decision-making process pertaining to the regulatory process and related challenges are discussed. Lastly, the dynamics surrounding the formulation of the biosafety bill as a desired regulatory instrument are analysed.

#### 5.2 Review of biosafety regulatory instruments

Regulation is a component of governance that is about steering the flow of events and behaviour (Braithwaite *et al.*, 2007). Regulatory instruments on the other hand empower decision making bodies in order to guide the steering process (Andanda, 2006). Biosafety regulations prior to the enactment of Biosafety Act 2009 (RoK, 1998 and the revised version RoK, 2003b) and the Act (RoK, 2009) are the official regulatory instruments used in the biosafety decision making matters and evoke some form of authority. However, there were other supporting instruments which were widely referred to by the interviewees in view of the concerns they elicited during implementation. All these regulatory instruments put together serve as benchmarks in interpreting the accounts of the interviewees related to regulations and regulatory practice. They are therefore analysed in the next subsections based on data-led

organising themes identified during coding which include the scope in terms of regulatory aim, approaches to risk assessment (RA) and decision-making processes.

### ***5.2.1 Cartagena protocol***

This is an international legally binding instrument providing guidance for cross-border handling of Living Modified Organisms (LMOs). As alluded to in Chapter two, it is the main motivation for most of the national efforts to establish a biosafety regulatory regime as an implementation obligation, Kenya being a signatory.

The protocol focuses on risk assessment (RA), risk management (RM) and risk communication (RC). RA refers to identification of potential environmental adverse effects or hazards; and determining when a hazard is identified, the probability of it occurring. RM refers to mitigation measures instituted to minimise the potential hazards identified using science based RA protocols.

The decision-making process pertaining to LMOs is based on an Advanced Informed Agreement (AIA) notification procedure, accompanied by a rigorous RA process. Annex III of the protocol details the RA procedure which is presumably science based but with precautionary elements and vague provisions for socio-economic considerations. Decision making period by respective member states includes 90 days acknowledgement of the AIA notification and 270 days for actual decision making after RA audit.

It is important to note that, the protocol came into force after Kenya had already initiated a regulatory regime in 1998 through the drafting of the first regulations discussed below. Consequently, the revised version (RoK, 2003b) was the first attempt to incorporate the provisions of the protocol, while subsequent efforts were geared towards legalising the already initiated biotechnology activities and regulatory instruments through an enforceable Act of parliament.

5.2.2 Regulations of 1998/2003 and Biosafety Act 2009

In relation to implementation, these instruments were intensely referred to by many interviewees. Thus, they are analysed and compared in Table (8) below based on different issues relevant to data presentation in this chapter. Key aspects that the analysis brings to the fore are weaknesses related to lack of clarity on different aspects of risk assessment (RA) guidelines and overall regulatory decision-making processes pertaining to trials approval and implementation. These weaknesses are particularly prominent with the instruments prior to the legalised Biosafety Act and form a substantive part of this chapter.

Table 8: Tabulated review of key regulatory instruments

Issue	RoK, 1998/2003b	RoK, 2009
Scope	Research trials under containment.	Containment & deliberate release.
Legal status	Lack legal authority.	Legally binding.
Decision-making procedure	Notification through NBC but lack well defined standards.	Clearly defined notification process through NBA.
	Guided by RA.	Guided by RA.
RA procedures & decision making	Based on available scientific information but with precautionary approach.	Based on technical & scientific information and uncertainty is handled through more information and appropriate RM measures.
	RA information obtained through responding to RA based questions in application form.	RA information obtained from applicant, regulatory agency reports and relevant social economic concerns from the public.
	RA audit risk-based but questions are broad (human & ecological safety). RA standards are minimum commensurate with level of risk (Biosafety Levels I-IV) but inadequate standards for field trials.	-RA audit is risk based but specific to type of application (contained/deliberate release). -Regulations to define specific standards are being developed to be appended to the Act.
Decision period	Not specified.	30 days after notification & 90-150 days for RA & decision-making process.
RM & reporting	-Measures imposed after RA and self regulation is emphasised. -NBC relies on regulatory agencies for enforcement. -No reporting guidelines during trial execution.	-RM measures imposed after RA audit. -Enforcement is through monitoring by biosafety officers from NBA & regulatory agencies.
Public participation & transparency	Emphasised but entrusted to NBC, emphasis is on prudence and openness with regards to information disclosure.	-Provided for during decision-making process pertaining to regulatory approval. -Public comments are to inform RA and decision-making process.
Implementation of the instrument	This has been achieved through IBCs & NBC.	Full responsibility of legally empowered NBA.
	-Membership of these institutions not specified but broadly qualified as private and public. -Members qualifications not specified.	Constitution of NBA membership-majority will be institutional representatives but with technical knowledge on biosafety and biotechnology.

In addition to the above major instruments, there were some supporting instruments reviewed next, that some interviewees in practice identified with. They augment the discussion advanced in this chapter.

### ***5.2.3 Application form for contained research of genetically modified crops***

RoK (1998) has provisions for an application form (referred to in the thesis as old form), detailing RA questions that applicants would use to prepare a RA dossier for regulatory approval. This form is also appended to the manual for handling requests involving GMOs (NCST, 2006b). The scope entails both containment and environmental risk assessment related questions. Many GP interviewees found certain requirements of this form cumbersome to implement due to seemingly irrelevant and repeated questions, which some found to be very technical and scientific.<sup>52</sup> Challenges encountered by users during implementation led to its review.

### ***5.2.4 Application form for confined field trial of genetically modified plants***

According to some scientist interviewees, this instrument arose out of a need to simplify the regulatory process for confined field trials (CFTs). The form entails RA questions related to a crop and purpose of application which relate to type of confinement measures required to minimise potential spread of the crop genetically modified (GM) material. Categorisation of confinement measures as either “genetic” or “material” distinguishes the type of questions asked and the corresponding RA information solicited. Genetic confinement serves to inhibit gene flow and the researcher or applicant is only required to provide physical and biological measures that restrict or contain gene flow like removal of floral parts (part 3). Material confinement serves to keep GM material out of food and feed pathways e.g. through fencing of trial site and proper packaging of GM material during handling (part 4). Part five consists of

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<sup>52</sup> Interviews with RSIn-GP9, RSPu-GP4, RSIn-GP2, RSPu-GP1, TAN-NSS2, ATBp-PS5 and TAI-NS10.



contingency plans on measures that are to be undertaken in case of unplanned or accidental release of GM material like spillage.

#### ***5.2.5 KEPHIS monitoring and inspection documents for field trials***

These documents were developed by KEPHIS to enhance management of field trials. The draft regulations for conduct of field trials of Genetically Modified Plants (GMPs) in Kenya (KEPHIS, 2004a) outlines detailed regulation and enforcement procedures at all stages of handling GM material. The Standard Operating Procedures (SOPs) & inspection manuals for conduct of field trials of GMPs in Kenya (KEPHIS, 2004b) are put together as a guidance document for inspectors and trial managers. KEPHIS (2004b) was being used by the trial managers for trials management in line with terms and conditions of approval by the National Biosafety Committee (NBC). It was also being used by inspectors for recording purposes whenever they went for inspection.

These KEPHIS documents seem to enhance understanding of all the minor details needed for implementation of the biosafety regulations and are specific for maize and cotton, reflecting the biology of each crop. They may therefore be interpreted to be technical documents, facilitating compliance with regulations and monitoring of trials.

#### ***5.2.6 Conclusion with respect to review of instruments***

Critical review of the regulatory instruments in line with accounts of the interviewees suggests certain unclear general weaknesses that include (among others) inadequacies of institutional mechanisms responsible for regulations implementation. To further understand these emerging issues and the underpinning factors, the subsequent discussion is based on these instruments as benchmarks. Thus, the next section is presented thematically based on how and why interviewees defined and perceived the regulatory instruments vis a vis the regulatory process.

### 5.3 Regulatory purpose defining nature of regulations

Many scientists described regulations from an “evolving” perspective based on the purpose they expected the regulations to achieve. They expected regulations to evolve in terms of formulation in tandem with science (technology) development, but in their view, the latter was progressing faster. To describe this irregular trend, one NSS interviewee commented: *“regulations are not evolving with science”* (TAR-NSS1, researcher & technology advocacy, international NGO, Feb. 2008). Reinforcing this view, another scientist noted:

*“Scientists have been doing biotechnology research for quite some time without the [regulatory] policy and the guidelines.”* (TRTp-NSS3, research & trade policy advisor, association of seed traders, Nov. 2007)

The expected evolution vis a vis the status quo was interpreted differently in line with different regulatory purposes as presented next.

#### 5.3.1 Legality

Simultaneous evolution of GE research and the biosafety system would enhance legality of research activities and regulatory process. A number of interviewees observed that regulations prior to the Act lacked legal backing or deterrent measures, a view shared by both scientists and non-scientists.<sup>53</sup> Civil society groups however, argued legality issues in terms of the perceived exploitation whereby the proponents of biotechnology would take advantage of the legal vacuum to advance their trade interests illegally, purportedly through research path:<sup>54</sup>

*“That is why I am saying that we are almost operating in a vacuum. We have laws which we refer to and these laws are not doing us any good. When we say about the science going ahead, people can just bring it and get it into the market. This is the kind of mix-up that we are in.”* (NGOco-NS4, consumers’ rights advocacy, NGO, Jan. 2008)

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<sup>53</sup> Interviews with RSIn-GP9, BIp-PS1, ATBp-PS5, LABp-NS8 and NGOco-NS4.

<sup>54</sup> Interviews with NGOof-NS1 and NGOco-NS4.

Legalising research activities was perceived to have many other advantages. It would set up and sustain a credible regulatory system hence enhance public trust.<sup>55</sup> It would also provide a legal basis for the existing regulations and guidelines:

*"The 1998 regulations, it is out of good will that we have said let science go on. But if lawyers took it up to challenge it, you would be told that there is no legal basis for these regulations."* (LABp-NS8, parliamentary counsel, Attorney General's chambers, Jan. 2008)

Some policy scientist interviewees however claimed that the legality aspect especially of the crop based trials had all along been addressed by supportive pieces of legislation that have been quarantine in nature.<sup>56</sup> This seemed to contradict the seemingly legal vacuum that other interviewees claimed existed.

### **5.3.2 Promotion of investment and good image**

If regulations were to evolve as anticipated, they would provide security for biotechnology investment.<sup>57</sup> A policy scientist supporting this view commented:

*"No strong investor can invest in a place where there is no legal framework. If the biosafety law is in place, those people who are interested in investing in biotechnology will look at the biosafety law and they will invest as per the law. But now no investor can come here and invest on biotechnology because he does not know how the law is."* (BIp-PS1, biosafety policy advisor, government agency, Jan. 2008)

While a NSS interviewee remarked:

*"Already a lot of people are waiting to bring in a lot of things like soybean feeds for pigs. Investors want these products brought but without the bill nothing [no investment] can happen."* (TAN-NSS4, technology advocacy, regional NGO, Oct. 2007)

Corroborating this view, an interviewee from the industry commented:

*"If the biosafety bill passes in the next one or two years to come, then the science that is in the pipeline will come out onto the market.....the bill shows you*

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<sup>55</sup> Interviews with TAR-NSS1, BIp-PS1 and ATBp-PS5.

<sup>56</sup> Interviews with PRp-PS10, ATp-PS3, PRp-PS4 and BIp-PS11.

<sup>57</sup> Interviews with RSIn-GP2, BIp-PS1, BIp-PS13, TAN-NSS2, TAN-NSS4, TAD-NSS6 and TRTp-NSS3.

*the route to market.*” (TAI-NS10, technology advocacy, biotechnology industry, Jan. 2008)

Evolution of regulations development alongside the research trials as many interested players would have wished to happen was also seen as a way of promoting Kenya’s good image in terms of biotechnology advancement, hence setting a good precedence locally and regionally.<sup>58</sup>

### **5.3.3 Enhancing confidence through safety considerations**

Some PS interviewees argued that regulations would enhance safety in addition to building confidence of scientists, motivating them and other technology developers to be innovative.<sup>59</sup> Inclusion of safety elements in the regulations was also seen as a way of promoting public confidence through addressing public concerns for safety.<sup>60</sup>

*“Without the bill, the scientists and all those who may want to use the biotechnology are still hindered because we do not have measures in place to give Kenyans the confidence that somebody is looking at what those people are doing and regulating to make sure they are safe....the bill has to be enacted for the policy to take root and give Kenya that direction to enhance development.”* (ARp-PS9, regulator, zoosanitary regulatory agency, Oct. 2007)

These views expressed by some policy scientists relating to regulation and safety mirrored those of non-scientist interviewees from the civil society. The only difference is that, the former seemed to balance their opinions about safety and benefits that could be attained through GE application as the above comment seems to indicate.

### **5.3.4 Enhancing government control**

Regulations development alongside technology development was one way of ensuring that the government remained in control of the contested biotechnology research as claimed by many scientists and some non scientists.<sup>61</sup> Control was to be achieved in

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<sup>58</sup> Interviews with RSPu-PS8, ATBp-PS5 and ABp-PS14.

<sup>59</sup> Interviews with BIp-PS13, RSPu-PS7 and ARp-PS9.

<sup>60</sup> Interviews with ABp-PS14 and ARp-PS9.

<sup>61</sup> Interviews with PRp-PS10, BIp-PS13, ABp-PS14, PRp-PS4, TAN-NSS2, FSp-PS12, NGOcs-NS3 and NGOco-NS4.

various ways. A senior government official (BIp-PS13) emphasised the need for this control to safeguard against technological imperialism which is nevertheless not a biosafety issue. Viewing regulations as instruments through which government may gain regulatory control is perhaps the reason why some policy scientists were careful in the way they approached regulations, which may have contributed to the slow evolution process. Corroborating this view, one senior policy interviewee emphasised the need for a cautious approach to regulating biotechnology research trials in order to deal with uncertainty:

*"If you want to have effective regulations, they should be precautionary. You are approaching the unknown and you must ensure that certain things are in place. Then if they do not work right, really you did everything possible."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

Scientists referred to in this section were in agreement that regulations if they evolved to a legal status, would further promote government control and institutional harmony in terms of regulations implementation and enforcement. Some non-scientists corroborating this view were confident that this was the only way institutional or regulatory operations would be streamlined, through government gaining control of the regulatory process.<sup>62</sup> A non-scientist supporting this view and emphasising the importance of a legal framework commented:

*"We are not against the technology but things cannot be done in a state of anarchy, there has to be order. We really want [government] to regulate imports of GMOs that come to the country and the handling aspects. If it is something that is meant for an enclosed environment, then it should be confined and not released into the environment like it is being done now. We highly suspect that GM materials have been released to the open environment but the authorities do not want to accept."* (NGOcs-NS3, civil society's rights advocacy, environmental NGO, Jan. 2008)

This analysis suggests that, regulations have a very important role to play in managing concerns linked to application of GE technology, especially with regards to institution of some form of control, confidence and trust.

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<sup>62</sup> Interviews with LABp-NS8 and TAI-NS10.

### **5.3.5 Concluding notes with respect to regulatory purpose defining the nature of regulations**

Regulatory purpose as a way of interpreting the regulations seemingly presents a need for some sort of protection, authority and space for economic progression in form of effective regulations, informed by incremental learning. The following section further explores another purpose-related view of regulations.

## **5.4 Narrow versus broad nature of regulations**

As analysed in Table (8), the scope of the regulations prior to the Act was narrow, covering only provisions for contained GM research, with very limited elaboration on open field trials. This was not a deliberate omission and was pre-determined. According to some interviewees who were involved in the early regulatory phase, there was already a consensus amongst the taskforce members drafting the regulations on what was expected - to facilitate scientific research only (and not commercialisation).<sup>63</sup> Despite this understanding, there were varying standards used to classify regulations prior to Biosafety Act as narrow or broad, and in most cases these analogies were used in reference to the draft bill (RoK, 2008a) that was under formulation during field work. In the following sub sections, the defining themes that qualified regulations as narrow or broad are analysed.

### **5.4.1 Research stage and research aim**

Many scientists perceived the regulations to be adequate for confined research (science) but inadequate to move science beyond research. These sentiments were corroborated by a number of non scientists. One GP interviewee noted:

*“So far at least they [regulations] allow us [researchers] to perform confined trials within the research centres. But now when you want to go to the next step, we cannot complete the research process.”* (RSPu-GP1, research scientist, PRI, Jan. 2008)

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<sup>63</sup> Interviews with TAN-NSS4, ATBp-PS5, PRp-PS4 and BIp-PS11.

While a PS interviewee reinforcing the same concern remarked:

*"Those regulations were developed in 1998 and so far they have served us as far as research is concerned. But unfortunately those regulations cannot take us further than the field trials."* (BIp-PS1, biosafety policy advisor, government agency, Jan. 2008)

A non scientist supporting views of scientists argued that RoK (1998) regulatory instrument impacted negatively on: *"research development by hindering potential researchers with an eye on commercialisation"* (DW-NS12). A senior policy interviewee further considered the existing regulations to be "blunt" and narrow in focus lacking innovative emphasis, stopping at science for knowledge (human resource capacity building), rather than science for economic use:

*"We have been talking about science and technology for development since 1977 and we have left out innovation.....if you develop a new plant, how are you going to use it? So we have very powerful human resource but which is not empowered in terms of policies and regulations."* (BIp-PS13, policy advisor, government agency, Oct. 2007)

These interpretations suggest that many interviewees longed for broad or all encompassing regulations to enhance continuity of research for economic gains.

#### **5.4.2 Cumbersomeness in enforcement**

Both practitioners and policy scientists reported frustrations related to the enforcement of the regulations prior to the Act. Challenges were encountered during risk assessment (RA) and decision-making processes, trials management and monitoring. Thus, regulations were perceived to be undefined and therefore broad in focus. The old application form was supposed to guide applicants in RA requirements prior to submission of regulatory dossier for approval by the NBC. However, GP interviewees seeking trials approval found the application form very broad, asking what they perceived to be unnecessary questions for the intended confined research.<sup>64</sup> One of them described the process of completing a research application for regulatory approval as

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<sup>64</sup> Interviews with RSIn-GP9, RSPu-GP1, RSPu-GP4, RSAc-GP5 and RSIn-GP2.

similar to [*defending a PhD thesis*] (RSIn-GP9). Another scientist interviewee explaining the broad nature of the regulations remarked:

*"I think these regulations are even more than adequate ....we are actually implementing quarantine measures which more than adequately address the risks [and] are supposed to even deal with more serious organisms than GMOs."* (RSPu-GP1, research scientist, PRI, Jan. 2008)

These regulations implementation challenges were corroborated by other non-researcher interviewees.<sup>65</sup> One of them, a policy scientist, expressed his frustration with the old, cumbersome and purportedly broad application form that he felt was "*too scientific*" limiting his ability as a policy and regulatory advisor to guide applicants and researchers adequately (B1p-PS1).

The GP interviewees further perceived the supporting regulations from KEPHIS (2004a, 2004b) to be restrictive, limiting their freedom to manage field trials. A trial manager referring to the KEPHIS (2004b) regulatory instrument commented:

*"You do not have the freedom to manage the trial the way you want. If only some things can be made easier, management can be easy"* (RSPu-GP8, research scientist, PRI, Dec. 2007).

Because of challenges encountered in implementing various aspects of the regulations prior to the Act, a number of both GP and PS interviewees suggested that revision should incorporate user experiences. The revised application for confined field trials was one of the outputs of this recommendation.<sup>66</sup>

#### **5.4.3 Uncertainty and safety**

Interviewees' interpretation of caution and safety seemed to define the focus of regulations. As mentioned elsewhere, a number of PS interviewees admitted that the existing regulations adopted a precautionary approach. Consequently, some interviewees felt that, in this safety conscious form, regulations were restricting

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<sup>65</sup> Interviews with TAN-NSS2, B1p-PS1 and TAI-NS10.

<sup>66</sup> Interviews with PRp-PS10, RSIn-GP9 and B1p-PS1.



research.<sup>67</sup> From this point of view, regulations based on uncertainty were narrow in focus for failing to capture science transfer through commercialisation:

*"I have no problem with anybody advocating for precautionary principle. But you do not want to be careful to the point of death. You can be so careful that you do nothing [fail to progress in research]. Caution yes, but reasonable caution." (RSPu-PS7, researcher & policy advisor, PRI, Nov. 2008)*

Some non-scientist interviewees linked to pro-biotechnology organisation echoed similar sentiments with one describing regulations as overly cautious and narrow in focus (TAI-NS10). He linked this to uncertainty and negative perception that the public and policy makers seemed to have about GMOs. Interviewees from the civil society were sceptical about safety and social economic aspects of GM technology and hence found the regulations to be narrow in focus for failing to address these aspects.<sup>68</sup>

#### ***5.4.4 Conclusion with respect to narrow & broad view of regulations***

Narrow and broad concepts in defining nature of regulations seem to suggest value and interest based perceptions, shaped by the prevailing circumstances or experiences related to the regulatory process. To explore these emerging aspects further, the next section turns to interviewees' views and interpretations around the regulatory process.

### **5.5 Approaches to risk assessment (RA) and decision making**

The regulatory instruments discussed in Table (8) seem to emphasize science based RA procedures towards what would be perceived to be an objective decision-making process. In practice however, many interviewees noted that the overall trials approval process, decision-making process and subsequent implementation of decisions have been highly ineffective, attributed to different factors discussed below. One thing they seemed to agree is that the decision-making process was initially slow at the initiation of GM activities but improved considerably due to technological and policy learning

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<sup>67</sup> Interviews with RSIn-GP2, RSPu-PS7 and RSPu-GP4.

<sup>68</sup> For instance patenting of seeds, loss of biodiversity and allergenicity (interviews with NGOs-NS3, TAD-NS11 and NGOf-NS1).

linked to improved capacity, familiarity and experience. The claims of inefficiencies and reasons behind these claims were however described in different ways as discussed in the following subsections.

### ***5.5.1 Risk perception and RA in decision-making processes***

Interviewees were in agreement that GE research presents potential risks and hence RA and consequent decision-making process should be based on the nature of risk. There were however differences amongst interviewees on how RA should be approached, reflecting different understandings of risk and how “unknown” risk should be quantified. To some, risk associated with GE technology is “perceived”, arguing that it is not substantially different from any other risk (for instance risk posed by non-GE crops).<sup>69</sup> Thus, RA should be assessed with this consideration in mind. They felt that failure to make a distinction between perceived and actual or quantifiable risk enhances fear in minds of people, which further confounds decision-making processes.

Some argued that risk associated with GE technology is not easy to quantify, whereas benefits can be assessed and quantified, and thus were of the opinion that evaluation of risk based on product rather than process of obtaining that product was predictable:<sup>70</sup>

*“If you have not been able to quantify that risk...you will still be talking about the possible or potential risk. I think the benefits are usually more obvious when it comes to the products that have been approved than trying to tell the people about the process itself.”* (TAN-NSS2, technology advocacy, international NGO, Jan. 2008)

A number of policy scientists were however sceptical about reaching an amicable decision based on RA driven by the “unknown” risks. Perhaps this is why they needed to exercise caution during the formulation of regulations and in evaluating applications for regulatory approval:

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<sup>69</sup> Interviews with RSPu-GP1, RSIn-GP3, RSIn-GP2, TRTp-NSS3 and TAN-NSS2.

<sup>70</sup> Interviews with RSPu-GP1 and TAN-NSS2.

*“Maximum caution must be given to all the process of introduction and research to ensure that we are within safe limit as far as the risk is concerned. There is a lot and there is no doubt about it that we really do not know and nobody wants to make any serious mistakes now. We really have no information on the repercussions if something seriously went wrong.” (ARp-PS2, regulatory and policy advisor, MOA, Jan. 2008)*

This comment exposes an element of uncertainty which triggered some fear among policy makers, a factor that seemed to guide RA and consequent decisions around GM activities and management. Fear of the unknown among some PS interviewees could be aligned with views of the civil society interviewees about risk associated with GE technology. However, there were differences in the way risk posed by this technology was interpreted. Without specific reference to GE science, some non-scientists interpreted risk in a broad way and some had the following to say:

*“When you are dealing with anything new...you try to think about the possible risks that you may be putting yourself to” (NGOco-NS5, local NGO); “I perceive risk as something that I am not quite sure of, and that is how the ordinary Kenyan sees it” (JO-NS7, journalist, local daily).*

In contrast, some scientists could relate risk to the nature of research particularly field trials. Thus, risk in this context relates mainly to escape of transgenes from a confined area to an unintended area and the consequent harm that may arise thereof.<sup>71</sup> They argued that this type of risk can be addressed through appropriate, technically sound risk management (RM) measures imposed on field trials.

Some policy scientist interviewees had a problem with RA that seemed to emphasise negatives (risks) more as opposed to the open and balanced view that takes cognisance of both risks and benefits.<sup>72</sup> This imbalance may explain why the regulatory instruments discussed earlier have been formulated with risk and safety in mind as confirmed by the following remark from a senior regulatory scientist:

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<sup>71</sup> Interviews with RSPu-GP4, RSIn-GP3 and RSPu-GP1.

<sup>72</sup> Interviews with PRp-PS4, ARp-PS9, ABp-PS14, ARp-PS2 and ATBp-PS5.

*"Most of our policies and regulations are actually based on risks but risk on the negatives. You do not say that I am coming up with these regulations to facilitate fast moving of GM-adoption of GM products in the country. You say, I am coming up with these regulations to guard against a, b, c, d. Most of the policies we have adopted the view, glass is half empty.... You always have to have caution....the question is that you are approaching the unknown."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

The pro-biotechnology non-scientist interviewees shared this same opinion as many scientists, arguing that existing approaches to RA and decision-making process adopted a risk prevention approach.<sup>73</sup>

Approach to RA from risk and safety perspective seems to have been reinforced in most policy documents discussed at the beginning of this chapter. The regulations and guidelines (RoK, 1998, 2003b) have repeatedly stated that biotechnology development and use may pose risk to human health and environment. Further, the biotechnology policy outlines the cautious guiding principle for biotechnology development. It states:

*"The precautionary approach contained in Principle 15 of the Rio declaration on environment and development forms the basis for biotechnology development [in Kenya]." (RoK, 2006a:9)*

Consequently, this risk principle and associated perceptions seem to have guided the drafting of the Biosafety Act<sup>74</sup> as emphasised by one member of the drafting team:

*"But I think the focus of the bill is and should be biosafety, will Kenyans be safe even as research on biotechnology continues?....to ensure all plants, Kenyans themselves and the environment are safe regardless of the type of work going on."* (ARp-PS9, regulator, zoosanitary regulatory agency, Oct. 2007)

Risk perception in defining the RA audits and decision-making processes hints at contested ways of judging risk. It however calls to mind non-technical factors like fear that influence the judgement. These aspects that seem to exacerbate approaches to objective decision-making processes are kept in mind for further investigation in Chapter seven.

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<sup>73</sup> Interviews with TAD-NS11 and TAI-NS10.

<sup>74</sup> Biosafety is defined in the Biosafety Act 2009 as "the avoidance of risk to human health and safety, and the conservation of the environment, as a result of the use of GMOs."

### 5.5.2 Challenges in RA, decision-making processes and trials management

Interviewees identified several challenges directly linked to how the regulatory process was advanced. Among other factors, one major challenge was lack of guidelines and/or clear procedures to guide both decision makers and researchers, and is given more space in this section. Tensions emanating from this challenge as different groups of scientists engaged in different regulatory processes and activities are analysed thematically, while expounding reasons behind the expressed opinions.

#### 5.5.2.1 Regulations and procedures lacking clarity

Under normal circumstances, clear rules are meant to offer benchmarks for procedural RA evaluation and decision-making processes thereof. This would consequently enhance consensus in trials approval process, reflecting a science-based decision-making process that would be interpreted as objective and effective as the regulatory instruments seem to indicate. Accounts of interviewees reflected a seemingly different picture with many complaining of unwarranted regulatory delays that caused tensions and frustrations.<sup>75</sup> One principal investigator lamented: *“we had to amend the whole contract because of the delays which are still there”* (RSPu-GP7, animal research scientist, PRI, Jan. 2008). Meanwhile, an NBC member explaining the reason for the delays commented:

*“The application process was partly delayed because the scientists did not get clear guidelines from the NBC.”* (TRTp-NSS3, research & trade policy advisor, association of seed traders, Nov. 2007)

One interviewee from the biotechnology industry in relation to impacts of the delays commented: *“a big frustration has been the time delay. Companies look at time as money.”* (TAI-NS10, Jan. 2008)

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<sup>75</sup> Interviews with RSIn-GP2, RSPu-GP1, RSAc-GP5, RSPu-GP7, RSPu-GP4, RSIn-GP9, RSIn-PS6, ATBp-PS5, TRTp-NSS3, TAN-NSS2, ARBp-PS16, PRp-PS10, NGOco-NS5, LABp-NS8 and TAI-NS10.

The repercussions and tensions linked to lack of clarity of regulations pertaining to different aspects of decision-making processes are presented below.

**Unclear institutional mandates:** Some regulatory delays were blamed on institutional bureaucracies and unclear institutional mandates, causing regulatory tensions.<sup>76</sup> A GP interviewee lamented: *"I feel that sometimes we are not clear about the roles of the IBC and NBC, and who is supposed to do what and when"* (RSPu-GP7, animal research scientist, PRI, Jan. 2008). Emphasising this further, some PS and NSS interviewees noted that unclear guidelines aggravated institutional frictions, suspicion and misunderstandings amongst scientists in different institutions regarding how RA should be advanced. This hampered the decision-making process particularly at the early regulatory phases.<sup>77</sup>

*"There is in-fighting between people representing certain institutions which I have to regulate as the chair [of KARI-Institutional Biosafety Committee]. Attempt to impose more stringent regulations on the other party [research institution] always brings some [institutional] frictions. These disagreements became highly personal."* (ATBp-PS5, technological & biosafety policy advisor, public university, Nov. 2007)

According to Table (8) and RoK (1998), operations of the NBC were designed to be institutional in nature, but analysis presented here suggests inability of this form of design to deliver the intended regulatory guidance and institutional harmony.

**Contested NBC representation:** Clear regulations are also meant to provide legally binding guidelines on nature of membership of the NBC committee and attendance of meetings. These important requirements are lacking in the regulatory instruments. To a number of interviewees, this caused tensions, constraining the decision-making process even further.<sup>78</sup>

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<sup>76</sup> Interviews with RSPu-GP1, RSIn-GP2, RSIn-PS6, PRp-PS10 and RSPu-GP7.

<sup>77</sup> Interviews with ATBp-PS5, ATp-PS3, TAN-NSS2 and ARBp-PS16.

<sup>78</sup> Interviews with ATp-PS3, BIp-PS1, ARBp-PS16 and PRp-PS10.

*"NBC members are not employees of the government [NCST]. They are all coming from different organizations and sometimes to get people to a meeting can be quite tricky. There are times the NBC had to cancel meetings due to unavailability of members."* (PRp-PS10, regulator, phytosanitary regulatory agency, Jan. 2008)

Unclear guidelines were observed to be the cause of undefined NBC membership, making it quite large.<sup>79</sup> The issue of contested representation was corroborated by some non-NBC interviewees from the civil society.<sup>80</sup> One observed:

*"There are so many research scientists [at the NBC] who are on the science but others like the social scientists are not well represented....we only have one farmer and one consumer representative."* (NGOcs-NS3, civil society's rights advocacy, environmental NGO, Jan. 2008)

What seemed to be emerging is the assumed view that non-scientific community like farmers or consumers should only be represented by social scientists. However, institutional representation at the NBC was paramount as a democratic right, allowing a wide range of views<sup>81</sup> as the then NBC chair seemed to reinforce: *"as it is right now, NBC reflects the diversity of the interests groups whose interests must be properly represented"* (ATp-PS3, Nov. 2007). How these different interests should be legitimately represented was nevertheless contested as discussed next.

***Unanimity as democratic decision-making process:*** Democracy was equated to unanimity and was the decision-making style of NBC in practice, as described by the then NBC chair:

*"NBC is a very heterogeneous committee. If there is a voice that says no [to a particular RA issue], then you may have to suspend that [application] until we all come to an agreement"* (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007).

This style of decision-making process was confirmed by a GP researcher who has been an applicant, with vast experience in the Kenyan regulatory approval process:

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<sup>79</sup> Interviews with TAR-NSS1, TRTp-NSS3 and TAN-NSS2.

<sup>80</sup> Interviews with EPA-NSS5 and NGOcs-NS3.

<sup>81</sup> Interview with BIp-PS1, ATp-PS3 and documents of NBC meetings obtained from NCST.

*"The way NBC votes and decisions are made is not right where it has to be unanimity....It should be structured in such a way that probably; if three quarters agree, the rest [disagreeing] quarter are asked to appeal, but not unanimity. Even the current chairman I saw him doing the same."* (RSIn-GP2, research scientist, IRI, Dec. 2007)

Different disadvantages associated with this style of decision making were noted. Some felt that it made the process prone to interests and value-led judgement:<sup>82</sup>

*"The way decisions are made....it again comes to the risk of regulator making the wrong decision. I know when you do not have a structured way of making decisions; then the person who talks the roundest, the person who has the most interest, carries the day."* (RSIn-GP2, research scientist, IRI, Dec. 2007)

It also made consensus difficult to be achieved on various aspects of the decision-making process including RA, a view shared by some non-scientist interviewees. One of them from the industry noted:

*"Within the IBC and the NBC, sometimes you get dissenting voices in every process and this can delay things as people try to develop that consensus. A better system would be two thirds majority or three quarter majority system in order that decision making can be more expeditious."* (TAI-NS10, technology advocacy, biotechnology industry, Jan. 2008)

The analysis presented here brings to mind the contention between democratic decision-making process and unanimity in an attempt to uphold democracy. This style of engaging actors in the regulatory process requires further investigation with respect to balancing diverse interests and achieving legitimacy.

**Objectivity & constrained independence of scientists:** There was consensus among many scientist interviewees that the decision-making process advanced by NBC should be objective and guided by science. However in practice, this was impacted upon by different exogenous factors (like institutional obligations) that limited neutrality. This was linked to unclear benchmarks that were perceived by some interviewees to be exposing the regulatory process to subjective judgements.<sup>83</sup>

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<sup>82</sup> Interviews with RSIn-GP2, RSPu-GP1 and RSIn-GP9.

<sup>83</sup> Interviews with RSIn-PS6, RSIn-GP2, BIp-PS11 and RSPu-GP4.



Although NBC is made up of heterogeneous scientists who are relied upon to guide the process, the academic scientists were perceived to be neutral and fair in their biosafety related judgements. This was linked to the view that they are teaching/academic oriented and less research or policy oriented, hence no conflict of interests:

*"I think the NBC should have more independent scientists in it, to give very independent scientific views without representing the views or perceptions of any institution.....as people who participate in the NBC in their independent personal capacity as scientists and not representatives from institutions. They can give their views without fear of redress by their institutions or without being quoted as having represented the institution view. There are certain things other [non-academic] scientists will not say because they are sitting in those committees on behalf of their institutions. Their views may be influenced by the position that has been taken by their institutions. I think I would trust academic institutions [& scientists] with independent views a lot more than scientists who come from other institutions that are research based."* (RSIn-GP3, research scientist, IRI, Mar. 2008)

Indeed, one academic scientist who held the position of the NBC chair during field work was perceived to be fair: *"the new chair listens to all stakeholders' views including applicants, leading to fair and balanced decisions"* (RSPu-GP4, Nov. 2007). This comment reaffirms the above observation.

Perhaps confirming the institutional related conflict of interests, many NBC members admitted that as they deliberated on biosafety issues at the NBC, they endeavoured to safeguard interests of their institutions, rather than their own individual views. An interviewee from civil society confirming this commented: *"I attend NBC meetings as a representative of consumers; I never take my personal interests"* (NGOco-NS5, local NGO, Jan. 2008).

As much as NBC members were perceived to be fronting institutional opinions, there are others who had observed that decisions at NBC are more individual-based rather than institutional-based.<sup>84</sup> This contradicts the preceding view, but nevertheless reflects

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<sup>84</sup> Interviews with RSIn-PS6 and ATBp-PS5.

a process that is value laden (institutional or individual based) due to nature of the subject under deliberation as emphasised by one NBC member:

*“Because I sit at the NBC, I can say most of the NBC people try to work with facts and data. But the facts and data available vary....when it comes to GMOs it depends on which area somebody subscribes to. NBC uses scientific reasoning but it is an area of science whereby the scientific reasoning is very varied. Some people are liberal, some are still conservative.”* (RSIn-PS6, general health & safety advisor, IRI, Nov. 2007)

Scientists seemed to prefer separation of scientific issues from social issues, especially in risk evaluation.<sup>85</sup> However, some noted that the decision-making approach adopted by NBC seemed to accommodate social aspects that confuse decision makers and complicate the regulatory decision-making process:

*“I know a number of applicants and applying institutions still feel that the NBC’s practice of [risk] evaluation and eventual [application] approval process is not fully guided by scientific evidence. Occasionally there are introduction of other factors outside regulatory - ethical, social and other attitude based issues. Depending on composition of the NBC, I know applicants have expressed this feeling that certain NBC members introduce other issues that are not science based.”* (ATBp-PS5, technological & biosafety policy advisor, public university, Nov. 2007)

Confirming this approach, the then NBC chair argued that non-scientific issues are considered and weighed against scientific facts during regulatory approvals and final decision making (ATp-PS3, Nov.2007). This attempt to incorporate social issues again constrains a purportedly objective decision-making process.

Scientific or science-based approach to decision-making process was further constrained by non-technical aspects like “fear” linked to sensitivity of GE technology, but which nevertheless affected ability of regulators to make independent judgement:<sup>86</sup>

*“The problem with regulations and the regulatory system in Africa which is still developing, the individual person as the regulator has a problem because you fear that if I allow this GE trial and something goes wrong, you will be the one to be slaughtered. So the fear that you might get cheated and you do the wrong*

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<sup>85</sup> Interviews with RSIn-GP9, RSPo-GP6, ATBp-PS5 and TAR-NSS1.

<sup>86</sup> Interviews with RSIn-GP2, RSPu-PS7, PRp-PS4, RSIn-GP9, RSAC-GP5 and ARp-PS2.

This observation was corroborated by non-scientist interviewees who sit at the NBC, but thought that this unwarranted fear could be resolved through legally binding regulations to guide and protect the decision makers.<sup>87</sup>

Despite these contestations, many interviewees believed that the overall decision-making process by the NBC has been fairly objective, guided by science-based risk assessment audit, where views and interests of all members (institutional or personal) are considered.<sup>88</sup> However, there seemed to be different understandings between democratic-based thinking and the science-based and objective line of argument. The latter is the cornerstone of the regulatory instruments discussed earlier, replaced by the former undefined value-laden practice as narrated by interviewees. This disparity is explored further in Chapter seven.

***Lack of clarity in RA procedures and reporting:*** Some GP interviewees involved in research trials used the following phrases to describe lack of clarity of RA information demanded from applicants through the application forms: "*unrealistic demands, adhoc, unclear, strict and not user friendly.*"<sup>89</sup> Policy scientists responsible for formulating regulatory instruments also found some aspects of the regulations prior to the Act too cumbersome to enforce particularly during RA and decision-making processes. One PS interviewee referring to the old application form made the following comment:

*"I don't know who came up with the first [application] form because it was complex. Most of the applicants I think were lacking capacity to interpret [those questions] on the form. Even the NBC members could not interpret them because they were too scientific."* (BIp-PS1, biosafety policy advisor, government agency, Jan. 2008)

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<sup>87</sup> Interviews with LABp-NS8 and NGOco-NS5.

<sup>88</sup> Interviews with FSp-PS12, BIp-PS1, ABp-PS14, PRp-PS10, ARBp-PS16, ATp-PS3, LABp-NS8, NGOco-NS5 and TAI-NS10.

<sup>89</sup> Interviews with RSAc-GP5, RSPu-GP4, RSIn-GP9 and RSIn-GP2.

Some interviewees confirming this anomaly argued that inadequacy of the existing regulations to guide in RA prompted reliance on RA data generated elsewhere.<sup>90</sup>

Perhaps because of the difficulties encountered during RA and decision-making processes, interviewees reported accounts of attempts to address the regulations inadequacies. For instance the old application form was found to be inadequate for field trials (CFTs) and consequently revised *“to make it user friendly”* (PRp-PS10, Jan. 2008).

Regulations also lacked clarity on how RA information and field trials reports should be handled as reported by some GE interviewees and corroborated by some PS interviewees.<sup>91</sup> This could have an implication for subsequent decisions that were purportedly supposed to be informed by experiences of previous trials. How then would continuity be enhanced if trials activities are not reported to the decision makers accordingly and not properly documented for future reference?

The accounts reported here seem to expose a disconnect between technical or scientific information (like biology of cotton) that was needed to guide RA process, and subsequent decision-making processes. This implies that the information solicited for RA through the old application form did not reflect the practical situation that should be guided by technical aspects of the regulatory instruments.

**Regulatory costs:** A number of interviewees mainly practitioners and some policy scientists considered the regulatory approval process to be costly.<sup>92</sup> They associated this with unclear regulatory guidelines that lacked structured payment fees to guide researchers and potential applicants:

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<sup>90</sup> Interviews with RSPu-GP7, RSIn-GP9 and BIp-PS1.

<sup>91</sup> Interviews with RSIn-GP2, RSPu-GP4, ARp-PS9, BIp-PS1 and PRp-PS10.

<sup>92</sup> Interviews with RSPu-GP4, RSIn-GP2, RSAC-GP5, ATp-PS3, PRp-PS10 and TAI-NS10.

*“There are no guidelines for payments, how much and who should pay and all that. It should be clear and there must be some information somewhere given to applicants saying these are the charges from the beginning.”* (RSPu-GP4, research scientist, PRI, Nov. 2007)

The costs were linked to undefined and unpredictable cost of paying risk assessors and decision makers attending the IBC and NBC meetings. For instance and as reported elsewhere, NBC members had to be enticed to attend meetings through payment of participation allowances and other allowances like transport costs and RA audits.

Lack of predictable decision making timelines, and the fact that reaching an agreement was time consuming and challenging implied that unplanned NBC/IBC meetings would be held. This tended to escalate regulatory costs, a view that was corroborated by a non-scientist interviewee from the industry (TAI-NS10, Jan. 2008).

#### **5.5.2.2 Conclusion with respect to unclear regulations & guidelines**

From the narrative presented in this section, tensions caused by inadequate or lack of clarity of regulations qualify the approaches to RA and decision-making processes adopted by decision makers as inefficient. One thing to note here is that challenges were experienced among different actors irrespective of whether in policy or practice. This seems to confirm some aspects of the nature of regulations discussed previously like enforcement difficulties. What may not be clear from the analysis is the impact of the reported challenges on the eventual decisions arrived at, in terms of acceptability or implementation by the wider scientific community (e.g. researchers or regulators). This is revisited in the next chapter.

Besides these technicalities, it is important to note that values and interests as non-technical factors confounded the decision-making processes and are explored further in Chapter seven. Despite this, many interviewees felt that, guidance of an effective decision-making process depends on clear regulations and guidelines.

There were other factors which seemed to complicate the RA and decision-making processes even further as explored in the next subsections.

### 5.5.2.3 Capacity issues

At the commencement of modern biotechnology activities in early 1990s, inadequate technical understanding of biotechnology and biosafety is perceived to have contributed to inefficient and delayed decision-making process. This early capacity challenge was experienced by individual scientists and institutions responsible for certain aspects of the decision-making process, both at practice and policy level.<sup>93</sup>

All the six GP interviewees who have been applicants cited incompetence of NBC members in dealing with biosafety and biotechnology matters. This made some of the members to ask what was interpreted as embarrassing and non technical questions, which also reflected lack of seriousness and commitment.<sup>94</sup> This incompetence was also echoed by some NBC members with one of them noting: *"members were not adequately trained to undertake or to clearly make decisions on these highly scientific applications."* (TRTp-NSS3, Nov. 2007)

Another aspect that was raised by some interviewees was the technical incompetence of head of institutions involved in regulatory processes which is however a political issue, since they are government appointees. This was perceived to be another factor affecting smooth and politics-free decision-making process.<sup>95</sup>

The bureaucratic process that contributed to delayed decision-making process was also partly linked to inadequate and limited institutional capacity within regulatory agencies and the Institutional Biosafety Committees (IBCs). IBCs according to RoK (1998) were

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<sup>93</sup> Interviews with ATp-PS3, PRp-PS4, ARp-PS2, ARBp-PS16, PRp-PS10, BIp-PS1, RSIn-PS6, ABp-PS14 and ATBp-PS5.

<sup>94</sup> Interviews with RSPu-GP4, PRp-PS10, BIp-PS1 and TAN-NSS2.

<sup>95</sup> Interviews with RSAC-GP5 and RSPu-GP4.

supposed to technically backstop the NBC's decision-making processes, but this was hampered by inadequate, technically qualified human capacity:<sup>96</sup>

*"The IBCs were not thorough enough to have the application technically sieved and so the NBC would then refer the issues back and this tended to frustrate some of the scientists." (TRTp-NSS3, research & trade policy advisor, association of seed traders, Nov. 2007)*

Non scientists also felt technically deficient to contribute to the purportedly scientific decision-making process of the NBC as expressed by a molecular scientist interviewee from the civil society:

*"The representatives of KENFAP and CIN sitting at the NBC are not adequately informed as such and do not contribute effectively to the debate. In most cases they are ill-prepared and do not represent the views of stakeholders. The common perception of scientists is that the issues are too technical for non scientist to understand." (EPA-NSS5, environmental protection advocacy, civil society, Jan. 2008)*

Perhaps inadequate capacity may have contributed to what some interviewees referred to as multi-tasking where the limited number of experts perceived to be technically competent in biotechnology and biosafety matters assumed multiple roles. For instance, RSPu-GP1 is a practitioner in a research institution; she is also a member of the NBC and also secretary to one of the Institutional Biosafety Committee. When asked how these different responsibilities impact her expert's role, she admitted that in a normal situation she should not be multi-tasking, but lack of capacity within her institution was causing this. Capacities referred to by this interviewee were biosafety, molecular science skills and ability to play out these roles in a highly politicised environment. There were also different scientists multi-tasking as "experts" by the virtue of being academic scientists and policy makers at the same time. Many interviewees involved in

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<sup>96</sup> Interviews with MK-PS14, TRTp-NSS3 and BIp-PS1.

this study had at one time in their careers held several positions or were holding policy positions as scientists.<sup>97</sup>

As much as many interviewees understood the importance of attaining certain level of technical capacities for enhanced and objective decision-making processes especially biosafety risk assessment, regulatory instruments were expected to give guidance on expected technical qualifications. Without giving details, some of the regulatory instruments analysed at the beginning of this chapter emphasise that risk assessors and those implementing RA decisions should be technically qualified. RoK (1998) in particular states that, persons and organisations engaging in biotechnology operations must be:

*“...fully familiar with the risks to which biotechnology products expose the society and the environment in order to make proper judgement on the safety arrangements that they must put in place”* (RoK, 1998, executive summary).

The regulatory instruments are however either silent or vague about technical qualifications, an aspect that might perhaps be addressed in the regulations being drafted to be appended to the approved Act.

#### 5.5.2.4 Attitude

Some policy interviewees argued that some delays experienced in making decisions pertaining to regulatory approvals of GE applications may have been caused by the negative attitude adopted by research scientists towards biosafety regulations:<sup>98</sup>

*“We [NBC] have had nasty experiences with experienced researchers. But we tell them you are the ones who set them [regulations] and we do not doubt your ability as scientists, but this is a statutory requirement that each one of us [scientists] has to follow.”* (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)

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<sup>97</sup> For example, RSIn-GP9 has been a practitioner, regulator and now pro-biotechnology NGO employee. ARp-PS2 is a trained biologist who once worked with KARI, later joined KEPHIS and now a senior government officer in the Ministry of Agriculture. ARBp-PS16 is a plant breeder who worked with KARI and now is a lecturer in a local university (see also Appendix 1).

<sup>98</sup> Interviews with ATp-PS3, PRp-PS4 and ARp-PS2.



On the part of policy scientists, negative attitude towards GE as a new technology experienced at the initiation of biotechnology programme in Kenya also caused delays in regulatory deliberations.<sup>99</sup> One policy scientist, perhaps justifying this commented:

*“When it comes to biosafety and GMOs, everything was new to the majority and so, a little bit of caution is acceptable.”* (ATBp-PS5, technological & biosafety policy advisor, public university, Nov. 2007)

As suggested by this analysis, attitude as conceptualised by actors may constrain decision-making processes and can be linked to values discussed previously, and interests explored next. These aspects are kept in mind for exploration in later discussions.

#### **5.5.2.5 Different players and different interests**

Some interviewees expressed concerns that the decision-making process pertaining to regulatory process was being influenced by interests linked to individual scientists and affiliated institutions.

**Research interests:** Researchers were perceived to be bringing research interests into the decision-making process, a view expressed by many scientists and some non-scientists.<sup>100</sup>

**Government interests:** The government represented by various policy scientists was perceived to be interested in ensuring technology deployment, towards attainment of its vision.<sup>101</sup> In addition, the government through the NCST was perceived to be interested

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<sup>99</sup> Interviews with ARp-PS2, ATBp-PS5 and ARBp-PS16.

<sup>100</sup> Interviews with RSIn-GP9, RSPu-PS7, RSPu-PS8, RSIn-GP2, TAR-NSS1, LABp-NS8, NGOf-NS1, NGOf-NS2, RSIn-PS6, ATBp-PS5 and TAI-NS10.

<sup>101</sup> Kenya Vision 2030 is Kenya's new development blueprint based on three pillars one of which is "economic" pillar (RoK, 2007b). It is the follow up of the Economic Recovery Strategy for Wealth and Employment (ERS) (RoK, 2003a) that has been implemented since 2002.

in providing a legal framework for biotechnology investment in the country in compliance with international protocols.<sup>102</sup>

**Trade related interests:** Many scientists and some non scientists were concerned that GE technology is linked to trade interests as opposed to needs of the public.<sup>103</sup> Some described these trade linked interests as “business” involving money, cementing the relationship between trade, politics and power. One scientist commented:

*“biotechnology is more the money and money is power”* (RSPu-GP7, PRI, Jan. 2008)

while a non scientist interviewee noted: *“at the end of the day, I think everything points towards trade”* (LABp-NS8, parliamentary counsel, Jan. 2008). These political factors are likely to dominate any decision-making process.

The possibility of different interests infiltrating or informing the decision-making processes is an issue that warrants further investigation in view of the impact this could have on the regulatory process and instruments. It is therefore taken up elsewhere in various parts of this thesis.

## **5.6 Biosafety bill in achieving the desired regulatory purpose**

The foregoing analysis suggests various shortcomings related to regulatory instruments and regulatory practice that resulted into various challenges and tensions as scientific actors engaged in the regulatory process. The majority was however optimistic that a biosafety bill would address these shortcomings, enhancing what was expected to be an efficient regulatory process.<sup>104</sup> In this section, developments, emerging issues and controversies surrounding the biosafety bill formulation process are discussed (see also Appendices 7 & 9). The section concludes with an analysis of the approved Act in the context of the weaknesses linked to the previous draft version (RoK, 2008a).

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<sup>102</sup> Interviews with RSIn-PS6, ATBp-PS5, BIp-PS1, JO-NS7, NGOco-NS4 and TAI-NS10.

<sup>103</sup> Interviews with TAD-NSS6, ABp-PS14, BIp-PS1, BIp-PS13, TRTp-NSS3, RSIn-GP3, RSPo-GP6, RSPu-GP7, LABp-NS8 and NGOcs-NS3.

<sup>104</sup> Interviews with BIp-PS1, PRp-PS10, RSPu-PS7, RSIn-GP9, RSIn-GP2, RSPu-GP7, RSIn-GP3, BIp-PS13, ARp-PS9, BIp-PS11, ABp-PS14, ARp-PS2 and FSp-PS12.

### 5.6.1 *Contested representation and transparency in bill formulation process*

Many interviewees expressed their support for inclusion of all stakeholders in formulation of biosafety policies because of the inherent broader social issues.<sup>105</sup> One aspect that some thought had been previously ignored during the drafting of the first regulations was involvement of social scientists and consequently the exclusion of social aspects. Some scientists however were of the opinion that science issues needed to be handled separately from social and ethical issues. This being the case, the scientists drafting the bill were to exclude aspects that were purportedly not science-based and difficult to regulate. One scientist explaining the reason for this view commented: *“we should not allow social issues that cannot be regulated to block the science”* (TAR-NSS1, international NGO, Feb. 2008).

Non scientists from civil society on the other hand did not approve of the seemingly scientific approach and consequently labelled scientists as “scientific” lacking social perspective.<sup>106</sup> One referring to the drafting of the biosafety bill commented:

*“I could read clearly that the bill is scientists’ work. I do not blame the scientists because to them they see things that way. They say they want to improve the farmer’s life and all that, but at the same time I think they are really not looking at the issues from the farmers’ perspective.”* (NGOf-NS2, farmers’ rights advocacy, Nov. 2007)

But how social and scientific issues could be balanced and different stakeholders engaged effectively in the policy process to the satisfaction of all players was a contested issue. In the section discussed below, two camps (opponents and proponents) were suspicious of each other revealing conflicts, mistrust, suspicion and lack of transparency related to engagement of stakeholders in the bill formulation process. The opponents (perceived to be bringing the social arguments) were viewed as “anti” and misleading the public and to the scientific community, they were perceived as against

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<sup>105</sup> Interviews with TAN-NSS4, TAR-NSS1, PRp-PS10, RSPu-PS7, RSIn-GP9, RSIn-GP2, NGOcs-NS3 and NGOf-NS2.

<sup>106</sup> Interviews with NGOcs-NS3, NGOf-NS2 and EPA-NSS5.

science (biotechnology). On the other hand, civil society interviewees were suspicious of GE technology and the scientists who they accused of being secretive in formulation of the bill. One of them reinforcing this view commented: *“when someone wants to hide some things, you make everybody to be suspicious”* (NGOf-NS2, Nov. 2007).

How the public should be engaged in the regulatory process has not been explicit until the Biosafety Act legally provided for public engagement especially in decision-making processes pertaining to deliberate releases of GMOs (RoK, 2009: Article 29).

#### **5.6.1.1 The proponents and opponents of the bill**

The way stakeholders were engaged in the policy process particularly the formulation of the biosafety bill exposed controversies that placed actors in “pro” or “anti” positions. On the one hand, the media and anti-GE activists were the opponents perceived to be either opposing the bill or impacting negatively upon its enactment, while on the other hand were scientists and their affiliated institutions (pro-biotechnology actors and government) as proponents. The majority of scientists expressed similar views with regards to the opponents, citing frustrations caused by their purportedly opposing actions. GP interviewees were more sceptical about the media when compared to the other scientists.

#### ***Perceptions of media***

Many scientists and some pro-biotechnology non scientists perceived the media and (the anti-GMOs activists discussed below) as having a major influence on public opinion on GE technology:<sup>107</sup>

*“Public perceptions on GE technology in Kenya are shaped a lot by the media and the public is basically skewed on their perception. The media has been largely influenced by the adversaries of GE technology, especially the Greenpeace and other NGOs.”* (RSIn-GP3, research scientist, IRI, Mar. 2008)

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<sup>107</sup> Interviews with RSIn-GP3, RSPu-GP4, RSPu-GP1, FSp-PS12, PRp-PS10, RSPu-PS7, ATp-PS3, ARBp-PS16, ABp-PS14, TRTp-NSS3, TAD-NS11 and TAI-NS10.

The views presented by most interviewees on media were linked to a media report regarding an occurrence of a purportedly scientific error at Kiboko open *Bt* maize field trial where the experimental *Bt* maize was erroneously sprayed with an insecticide.<sup>108</sup> This was viewed by some, including the Director of Agriculture (also referred to as Agriculture Secretary) as flouting of biosafety regulations and protocols:

*“The biggest mistake was the Agriculture Secretary going to the media without thinking about the sensitivity of the technology and the trials and what it was likely going to do. Now when it was in the media, it was open to all types of interpretations.....you could not filter out what was the issue and what was not...because when you tell the media you have stopped the trial, they interpreted that all GM research in Kenya had been stopped.”* (RSIn-GP2, research scientist, IRI, Dec. 2007)

Some of the scientists felt that, the media report mentioned here worsened the already negative perception about scientists and GMOs, citing sensitivity of GE technology.<sup>109</sup> Consequently, the scientist interviewees described media using different phrases like “ignorant”, “disinterested in GE” “out to make stories”, “produced sentimental report for the purpose of selling.”<sup>110</sup>

These arguments seemed to portray a hopeless and desperate situation that led to a kind of self reflection and an urge for behavioural change on the part of scientists as one PS interviewee pointed out:

*“The media is there to make stories...but otherwise, muzzling the media, has it ever happened anywhere? Let's be careful with our work. We can never be careful with the media.”* (ARBp-PS16, research scientist & biosafety policy advisor, public university, Mar. 2008)

This culminated into education of journalists on scientific reporting by pro-biotechnology NGOs like ISAAA and ABSF. Many interviewees perceived the training to be a way of enhancing responsible and informed reporting on biotechnology as one scientist pointed out:

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<sup>108</sup> “Government halts GM field trials” in the Sunday Nation, 28 Aug. 2005 by the director of agriculture.

<sup>109</sup> Interviews with RSIn-GP2 and TRTp-NSS3.

<sup>110</sup> Interviews with RSIn-GP3, FSp-PS12, PRp-PS10, RSPu-PS7, ATp-PS3, ARBp-PS16 and ABp-PS14.

*“Part of our awareness creation after the Kiboko incident [and the misleading media report] was to involve the media more and more, and also train them in responsible reporting.”* (ABp-PS14, technological & biosafety policy advisor, MOA, Feb. 2008)

The researchers and practitioners’ perceptions of media although triggered by this particular incident seem to be intimately connected to their values about GE science.

### *Perceptions of anti-GE activists*

Scientists expressed varying views regarding those perceived to be against GE technology. Many perceived them to be “ignorant”, “not sincere” and their arguments “not informed by facts”<sup>111</sup> To some scientists, the activists misunderstand the GE potential as well as scientists’ good economic intentions.<sup>112</sup> Several interviewees claimed that the activists were not interested in the content of the biosafety bill or its purpose (which was perceived to be addressing their unfounded fears), but rather in blocking GE technology since they have already formed a negative attitude about GMOs.<sup>113</sup>

In addition to misinforming and confusing public, some GP interviewees were concerned that the perceived unscientific proactive tactics used by anti-GE activists to discredit GE technology seemed to attract public attention (civil society groups demonstrating in the streets against the biosafety bill using placards was a case in point referred to by scientists).

Insincerity portrayed by anti-GE activists was associated with their links to environmental NGOs who were perceived to be funding their activities.<sup>114</sup>

*“The most unfortunate thing in Kenya is, the anti-GM groups...influenced more with opinions of international NGOs...who fund them to carry out*

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<sup>111</sup> Interviews with TAD-NSS6, TAN-NSS2, TRTp-NSS3, RSPu-GP8, RSPu-GP4, RSIn-GP2, RSIn-GP9, RSPu-PS8, PRp-PS4 and ARp-PS2.

<sup>112</sup> Interviews with RSPu-PS8 and TAN-NSS2.

<sup>113</sup> Interviews with ARp-PS2, Blp-PS13, Blp-PS11, RSPu-PS8, PRp-PS10, RSPu-GP1 and FSp-PS12.

<sup>114</sup> Interviews with ATp-PS3, ATBp-PS5, Blp-PS13, RSPu-GP4, RSPu-PS8, TAR-NSS1 and RSIn-GP2.

*advocacy....their major concern is to take a position of denial, a position that gives an advantage of criticism.”* (ATBp-PS5, technological & biosafety policy advisor, public university, Nov. 2007)

Some NSS interviewees appreciated the role the activists can play in the GE technology debate through positive criticism but perceive them to have inadequate scientific capacity to argue about science, and for some when the capacity is there they don't utilise it in order to “*keep their jobs*” (TAD-NSS6, Feb. 2008) and satisfy “*those financing their activities*” (TAR-NSS1, Feb. 2008).

Other scientists claimed that, opponents do not understand the process of law-making where details should be left out of the main Act for inclusion in the regulations that are usually appended to the law.<sup>115</sup>

Contrasting the views of the scientists, the civil society interviewees lamented that they were not potentially opposed to a biosafety regulatory regime, but rather the way the bill formulation process was being advanced by scientists, and some particular content of the bill (exclusion of social aspects). They cited incidences when they presented their views and concerns to the government for consideration but they were rejected, hence opted for a more proactive mode of expressing their views (demonstrating in the streets to attract public and politicians attention).<sup>116</sup>

In addition to the political nature of the bill formulation process, this analysis suggests that the proponents get angered by what they perceive to be anti-science tactics, adopted by opponents to fight GE science. Again this brings to the limelight their science-based values and interests. Many interviewees however hoped that the bill would reconcile the social and scientific issues, but were sceptical on how exactly it does that. This doubt seemed to be reinforced by the many concerns discussed next raised by a number of

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<sup>115</sup> Interviews with PRp-PS4, ARp-PS9 and RSIn-GP9.

<sup>116</sup> Interviews with NGOcs-NS3, NGOf-NS1, NGOf-NS2, NGOco-NS5 and NGOco-NS4.

interviewees regarding its shortcomings.

### 5.6.2 Concerns about biosafety bill 2008

The content was highly contested and the final document was seen as a product of science advanced by scientists, a perception that was echoed by a number of scientists and non-scientists. To some interviewees, the biosafety bill was a tool to advance GE science, while others interpreted the bill as narrow, focusing overly on GMOs (and not biosafety as implied) and inclined more to crops.<sup>117</sup> One regional expert reacting in relation to the content noted:

*"The bill the way it has been designed is mostly a bill against crop GMOs. It is not a real bill on biosafety in general...When you talk about biosafety; crop biotechnology is one of them. You should not develop a bill just around crop GMOs. This should be inclusive in which you have plants, animals, micro organisms."* (RSPo-GP6, biomedical research scientist, regional pro-biotechnology organisation, Mar. 2008)

While another senior policy interviewee remarked:

*"Biosafety should be looked upon beyond the GMOs and that is not properly addressed in the Act. The draft bill is concentrating more on the GMOs than on biosafety per se."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

Despite different perceptions related to use of the term "biosafety," some interviewees supported the use of the term, claiming that the concerns are about safety:

*"I think the focus of the bill is and should be biosafety. Will Kenyan be safe even as research on biotechnology continues to ensure all plants, Kenyans themselves and the environment are safe regardless of the type of work going on?"* (ARp-PS9, regulator, zoosanitary regulatory agency, Oct. 2007)

Some scientists supported the deliberate narrow nature of the bill, arguing that the legal framework (Act) can be sketchy on the understanding that actual implementation details are covered in the regulations.<sup>118</sup> Some scientists however were concerned that the bill

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<sup>117</sup> Interviews with RSPo-GP6, RSPu-GP4, PRp-PS4, RSIn-PS6 and ATp-PS3.

<sup>118</sup> Interviews with RSIn-GP9, PRp-PS4 and ABp-PS14.



ignores safety of final products and social aspects, a view which was also shared by many non scientists from the civil society.<sup>119</sup> Regarding this concern, one scientist noted:

*"We could have missed out the social science bit of it or the consumer bit of it....so that at least the bill really speaks also on social economic issues. You find that the bill is too scientific...when you talk about gene flow, it is actually social science, but someone needs to put it at the social science level because, even if gene flow is scientific, what you are protecting is social bit of it that is to do with changing and influencing the environment. So you needed someone who can speak on it from the sociology and economic bit of it, not just the science bit."* (RSIn-PS6, general health & safety advisor, IRI, Nov. 2007)

While a non scientist commented:

*"It [bill formulation] was so scientific. It took a very scientific approach without looking at the social, economic and environmental aspects."* (NGOcs-NS3, civil society's rights advocacy, environmental NGO, Jan. 2008)

Other issues that were raised by both scientists and non-scientists relate to inadequate enforcement mechanisms to enhance implementation of the bill.<sup>120</sup> Some of them noted that the government, although not well endowed in term of resources, should control the implementation process to enhance ownership (free of influence) and enhance public trust.

To put these concerns into context, the Biosafety Act is analysed in the next section.

### **5.6.3 Biosafety Act 2009**

The foregoing discussion although political and controversial led to the formulation of different versions of the biosafety bill that culminated into an Act in February 2009. The objective of the Act is to regulate activities in GMOs and to establish a predictable and transparent process of reviewing and making decisions on GMOs and related activities. It proposes establishment of a National Biosafety Authority (NBA) whose membership shall comprise of experts from various multi-sectoral representation. Unlike the NBC

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<sup>119</sup> Interviews with RSPu-GP7, RSIn-PS6, RSPo-GP6, NGOco-NS4, NGOco-NS5, NGOf-NS2, NGOcs-NS3 and NGOf-NS1.

<sup>120</sup> Interviews with EPA-NSS5, NGOco-NS4, NGOco-NS5, NGOf-NS2, NGOcs-NS3, LAEp-NS9, NGOf-NS1, RSIn-PS6, RSPu-GP1, ARp-PS2 and RSIn-GP3.

representation spelt out in previous documents, the Act has a provision for appointment of 3 experts in biological, environmental and social sciences, and one representative from the biotechnology industry. This statute seems to have addressed many of the concerns raised by interviewees in the preceding sections, pointing towards a potential for it to achieve the regulatory purpose desired by many interviewees. Some aspects still remain vague and it is anticipated that details will be captured in the regulations currently being drafted. However, inclusion of social and economic aspects has been incorporated in the decision-making process under Article 29. Further, the entire Act emphasises on safety and measures to manage potential risk.

## **5.7 Concluding remarks and chapter summary**

Despite the existence of regulatory instruments and what seems like an established regulatory structure (through the NBC), evidence in this chapter suggests that activities of the scientific community and the regulatory process were constrained by multiple technical and non technical challenges. Overall, regulations prior to enactment of Biosafety Act were perceived to be inadequate and regulatory practice inefficient in terms of decision-making processes. This seemed to slow or curtail technological development and enforcement of regulations. Arguably, this indicates some sort of institutional weaknesses. However, there were implicit social related issues that need further exploration in light of their potential to impact learning, knowledge production and overall scientific behaviour related to the implementation of regulations.

Regulatory practice is one focus of this thesis and the foregoing discussion related to institutional weaknesses provides an important context for the exploration of scientific behaviour. Further, tensions exposed in the process of actors' efforts to achieve a desired regulatory regime and the attitude related factors which are social in nature

warrant further investigation. As much as these factors impact technological progression, they seem also to have an impact on regulatory practice and process.

Table (9) below presents a summary of the findings and related emerging issues from this chapter that are pursued further in the subsequent chapters in order to understand how knowledge is managed in a regulatory context.

**Table 9: Summary of research findings on perceptions of regulatory process**

CHAPTER SUMMARY	
Issues	Findings/Perceptions
Regulations and perceived purpose	<ul style="list-style-type: none"> <li>-Regulations not evolving with science hence restricting technology deployment.</li> <li>-Regulations have narrow focus based on different interpretations.</li> </ul>
Nature of regulatory process, approaches to RA and decision making	<ul style="list-style-type: none"> <li>-The approach is based on caution and perception of risk associated with GE technology.</li> <li>-In theory the process is science-based guided by technically sound RA but in practice the process is inefficient hampered by technical and non-technical challenges some of which stem from unclear regulations and guidelines and inadequate regulatory capacities. Non technical aspects include attitude, interests and values.</li> <li>-Overall the process lack scientific objectivity and is value laden.</li> </ul>
Biosafety bill 2008 & formulation process	<ul style="list-style-type: none"> <li>-Tensions exposed in formulation process linked to unsatisfactory and poor public engagement mechanisms, exposing social &amp; scientific arguments.</li> <li>-Tension further exposes two counter groups in the regulatory process (proponent and opponents).</li> <li>-The bill as an instrument for reconciling the regulatory conflicts was not contested, but its content and context in terms of achieving this is contested.</li> </ul>

The next chapter endeavours to explore in details some issues raised in this chapter through a critical analysis of the role and behaviour of scientists in the regulatory process. This analysis is based on the different forms of knowledge that seem to emanate from the different activities they engage in, and how it is managed in the light of its potential to shape the regulatory instruments or the decision-making processes. This analysis is augmented by findings on perceptions of scientists on the regulatory practice and other data sources.

# 6 Role of Scientists in Shaping the Regulatory Process and Regulatory Instruments

## 6.1 Introduction

This chapter is a continuation of the previous chapter detailing perceptions of scientists related to regulatory practice that expose their role in the entire regulatory process. It should also be read in the context of Chapter two. The chapter addresses the second research question: *how scientists shaped the evolution of the regulatory process and instruments.*

Regulatory practice denotes activities that are relevant to the regulation of GMOs activities including instituting institutional arrangements for implementing those regulations (UNEP-GEF, 2004). Thus, the content of the chapter looks at a number of aspects that constitute regulatory practice: firstly, the activities related to regulations compliance in the management of GE research trials; secondly, the public communication and reporting on trials; and thirdly, the activities related to formulation of the regulatory instruments. In relation to this, *scientific/regulatory practice* refers to the role played by scientists in executing these broad regulatory aspects more generally. The regulatory instruments discussed in Chapter five have provided benchmarks on how the first two aspects could be analysed. They are however implicit about formulation of regulatory policies which is broadly bound up within risk assessment procedures (see Chapter five, section 5.2).

The chapter is presented thematically in three overlapping sections. The first section, in reporting the dynamics associated with scientific practice identifies different challenges and shortcomings related to the regulatory practice as well as motivations that drive this practice. This is followed by a discussion of scientific practice in relation to the

potential shaping of the regulatory process and instruments. The last section put into context the relationship between perceptions and practice, paving the way for further discussion about the implications of the scientific practice for regulatory policy and broader innovation process in the next chapters.

## **6.2 Dynamics associated with practice of scientists in implementation of regulations**

In the implementation of regulations, the scientific community interviewed encountered various challenges that impact upon the regulatory practice. These are discussed below after first exploring the reasons behind the motivations for engaging in the regulatory process.

### **6.2.1 Motivations: opportunities and interests**

A number of scientists observed that the initiation of the biotechnology research in Kenya caused hype and excitement among research scientists.<sup>121</sup> Biotechnology research therefore provided an incentive for scientists and some seized this opportunity for various reasons which include pursuit of knowledge and technology transfer as a national and social responsibility.<sup>122</sup> One scientist noted:

*"This drive by the scientists is because they have been given an incentive, motivated since the country needs food. [The policy makers] have also seen GE might be an answer and rely on scientists to help them. [This being the case], why wouldn't I [as a scientist], want to discover something for the country?"* (ARBp-PS16, research scientist & biosafety policy advisor, public university, Mar. 2008)

While one senior executive had the following to say:

*"Without saying we overstepped, we dared. I believed that it would have been irresponsible not to be involved in the quest for knowledge...in being part developers and part partners of understanding the knowledge chain and I had no intention of being left behind. It wasn't a personal curiosity. I think it was a national responsibility."* (RSPu-PS7, researcher & policy advisor, PRI, Nov. 2008)

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<sup>121</sup> Interviews with RSIn-GP9, PRp-PS4, RSIn-PS6, ARBp-PS16 and RSPu-PS7.

<sup>122</sup> Interviews with RSPu-GP7, RSPu-GP1, RSAC-GP5, RSPu-GP8, ARp-PS2, PRp-PS10, ATp-PS3, RSPu-PS7, RSPu-PS8 and TAD-NSS6.

Another practitioner shared similar views and emphasised that her quest for knowledge on GE technology was a societal responsibility to address their safety concerns and development related needs:

*"Most scientists do it for the scientific papers but for this [vaccine] trial...I need to know the kind of manipulation they have done and the likely events of that manipulation. I want to know what are the risks involved because I am the public eye. I feel that is what I can give back to the society to address our developing world problems...so there is that [societal] motivation, and motivation as a scientist to do good science."* (RSPu-GP7, animal research scientist, PRI, Jan. 2008)

Other factors that inspired scientists include personal gains like professional advancement, publishing and passion for fame. One scientist remarked: *"a scientist wants to be famous and recognized. It is not a crime to want to be famous"* (RSPu-PS7, Nov. 2008), while another commented: *"Some of them [scientists] they do it [biotechnology research] as a source of income."* (RSAc-GP5, Dec.2007)

Other interviewees claimed that they engaged in GE work due to the beliefs they hold regarding its potential, augmented by understanding of how GE technology works:<sup>123</sup>

*"Some are proponents just because they have been involved in one way or another, but there are a few who really believe in it and a few who really understand it enough, who have seen what it has done elsewhere."* (RSPu-GP1, research scientist, PRI, Jan. 2008)

While others seized the opportunity to become biotechnology advocates:

*"For some, their role is simply to debate and say biotechnology is good. Some just spend their time just doing that. Some of them are not even qualified to spend time in labs. They are able to understand it and so they can talk about it convincingly."* (RSAc-GP5, research scientist, public university, Dec. 2007)

Confirming some of the motivation claims by scientists, a number of non-scientist interviewees identified personal interests triggered by readily available resources (there

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<sup>123</sup> Interviews with RSPu-GP1, RSPu-GP7, TAR-NSS1, TAN-NSS2, RSAc-GP5 and RSPu-GP4.

is more money in biotechnology research as compared to basic research) and aspirations for fame as possible reasons that draw scientists to GE work:<sup>124</sup>

*"Scientists basically they want to do their work in the laboratory and come up with something, a result out of that research. But some scientists they just want to make a name and say I developed this. They do not target a bigger group of users."* (LABp-NS8, parliamentary counsel, Attorney General's chambers, Jan. 2008)

Some civil society interviewees reported that excitement and hype of the purportedly new science and the anxiety to engage in it contributed to the scientists "pushy" behaviour, linking this to personal interests and external pressure from their funding partners:<sup>125</sup>

*"GE is the in thing....you really do not want to be left behind. Our scientists are in a hurry. Some are doing PhDs...and they want to finish and get their certificates.....or they want to prove to whoever is sponsoring them that they have done something."* (NGOf-NS2, farmers' rights advocacy, Nov. 2007)

Some senior policy executives admitted that there was hype and anxiety to engage in GE research but argued that this was a way of testing the scientific and regulatory systems:<sup>126</sup>

*"Perhaps we were all anxious; perhaps we rushed a bit; keen to resolve some of the issues. There were questions at the beginning but we wanted to learn the process."* (RSPu-PS7, researcher & policy advisor, PRI, Nov. 2008)

Another senior policy executive corroborating the view on "hype" was concerned that scientists overlooked many technical and social factors that entail technology transfer:

*"So when we talk about the successes before even you pipette in the laboratory it becomes difficult, people saying that Africa will get out of hunger because of GM transformation and nothing had gone to the farm."* (RSPu-PS8, researcher & policy advisor, PRI, Jan. 2008)

Perhaps because of conflict between different motivations and opportunities presented by GE research, and the different challenges associated with biosafety regulations and

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<sup>124</sup> Interviews with JO-NS6, LABp-NS8, LAEp-NS9 and NGOf-NS2.

<sup>125</sup> Interviews with NGOf-NS2, NGOf-NS1, NGOf-NS4 and NGOf-NS3.

<sup>126</sup> Interviews with RSPu-PS7, RSPu-GP9, ATBp-PS5 and PRp-PS4.

implementation, the scientific community exposed certain varying behavioural practices. These relate to compliance with regulations during trials execution and communicating information emanating from the trials. These practices and the underpinning factors that qualify them as contested practices are analysed in the next subsections.

### **6.2.2 Non-compliance with regulations**

‘At the time of fieldwork, two field trials: *Bt* maize engineered to resist stem borers attack and transgenic sweet potato engineered for resistance to feathery mottle virus were extensively mentioned by the interviewees in connection with regulations non compliance (see Table 1 and Box 1 in Chapter one for detail of the context under which these trials were executed). Different interpretations explored below support interviewees’ claims of a non-compliant behaviour exhibited by mainly the research scientists involved in these trials.

#### **6.2.2.1 Lack of commitment by researchers**

Many scientist interviewees agreed that the scientists responsible for GE trials management showed lack of commitment by delegating this responsibility to research assistants, thus flouting the terms and conditions of regulatory approvals.<sup>127</sup> Referring to the transgenic sweet potato field trial, one former principal investigator confirmed that this delegation actually occurred (RSIn-GP9, Nov. 2007), while another regulatory scientist had the following to say about the *Bt* maize mismanagement at the Kiboko field trial site:<sup>128</sup> *“the trial was not handled properly...it showed some lack of seriousness on the part of the scientists.”* (PRp-PS4, Feb. 2008)

While a non state scientist interviewee referring to the same *Bt* trial reported:

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<sup>127</sup> Interviews with ATp-PS3, PRp-PS4, ATBp-PS5, TAD-NSS6, TRTp-NSS3, PRp-PS10 and TAN-NSS4.

<sup>128</sup> This refers to an incident in a *Bt* Maize field trial reported in Chapter five, section 5.6.1.1 & foot note 131.



*"The research scientist would have taken greater precaution; then a mistake like this could not have occurred. Admittedly there was a flaw."* (TRTp-NSS3, research & trade policy advisor, seed traders' association, Nov. 2007)

Research scientists' lack of transparency and commitment to trials management was corroborated by a number of non scientist interviewees.<sup>129</sup> One of them referring to the *Bt* maize trial remarked:

*"It was a gross mistake for [the concerned scientists] failing to follow the laid down procedures. Somebody looking at it broadly cannot believe on what the Kenyan scientist is doing if such an incident can take place. They [scientists] cannot convince us that they are following science-based procedures and protocols."* (TAD-NS11, technology advocacy, donor agency, Mar. 2008)

It was however pointed out by a number of scientists and non scientists that delegation of responsibilities to junior research assistants was inevitable because of limited biosafety capacity that leads to multi-tasking.<sup>130</sup> (See also Chapter five, section 5.5.2.3).

*"In this country with regard to this technology, we have very few scientists, that's a fact. The same scientist is a manager, he is a boss in his work station, he is also to represent the country in a scientific meeting in USA, Europe, S. Africa etc."* (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)

When practitioners were asked to comment about the non-compliant incidences related to the *Bt* maize and sweet potato trials,<sup>131</sup> they interpreted them as normative basic research experiences which many other scientists interpreted as good learning experiences.<sup>132</sup>

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<sup>129</sup> Interviews with JO-NS6, LABp-NS8, LAEp-NS9 and TAD-NS11.

<sup>130</sup> Interviews with RSPu-GP1, ATp-PS3, ATBp-PS5, TAD-NSS6 and TAI-NS10.

<sup>131</sup> The *Bt* Maize trial was erroneously sprayed with a systemic pesticide masking the effect of the *Bt* gene while the sweet potato trial was allowed to flower posing a danger of genes escape through pollination.

<sup>132</sup> Interviews with RSIn-GP9, RSPu-GP1, RSPu-GP4, ATBp-PS5, ARp-PS2, ABp-PS14, TAN-NSS4 and TAN-NSS2.

### 6.2.2.2 Scientists credibility and transparency questioned

The conduct of GE trials was perceived to require a substantial level of credibility on the part of scientists due to sensitivity of GE technology.<sup>133</sup> However, research scientists were perceived by a number of both scientist and non scientist interviewees to be untrustworthy and dishonest, perhaps leading to the non-compliant regulatory practice.<sup>134</sup> One senior regulatory executive referring to scientists' failure to promptly report the *Bt* maize incident mentioned elsewhere made the following comment:

*"If I cheat you once what would stop me from cheating the second time? Basically scientists concerned knew this is a [transgenic] trial, so how do you then spray with Furadan? Honestly, which type of scientist would do that? If you are honest, you will always tell the truth but if you are not, then it becomes very difficult in terms of regulatory and the science itself."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

A non scientist expressing similar concern about trials and transparency reported:

*"These guys [GE researchers] even with the guidelines given to them, they may not be following the guidelines and the products that we might get at the end of the day might have been produced with possible manipulations of one or two of the guidelines and regulations. Even science requires transparency. It is not only in politics."* (JO-NS6, journalist, local daily, Apr. 2008)

Perhaps credibility is one other aspect that regulations should be promoting. One senior policy executive emphasised the need for monitoring of research scientists as they implement trials claiming that: *"scientist...will do things that you cannot believe it is possible."* (RSPu-PS7, Nov. 2008)

Credibility was however found to be constrained by institutional obligations and compromises that both scientists in policy and practice were forced to make.<sup>135</sup> For example a senior policy scientist defending the reason why the sweet potato trial was approved despite its previously known shortcomings commented:

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<sup>133</sup> Interviews with ATp-PS3, PRp-PS4, ATBp-PS5, TAD-NSS6, TRTp-NSS3, PRp-PS10, TAN-NSS4, JO-NS6 and JO-NS7.

<sup>134</sup> Interviews with PRp-PS10, PRp-PS4, RSPu-PS7, RSPu-PS8, TAD-NSS6, TAN-NSS4, NGOf-NS1, NGOco-NS4, NGOf-NS2 and JO-NS6.

<sup>135</sup> Interviews with PRp-PS10, RSPu-PS7, PRp-PS4, RSIIn-GP9 and ARBp-PS16.

*"I knew of all these facts but I said we [NBC] let the sweet potato program go on because it is a guinea pig. It will show us how to manage the [science and regulatory] system. In retrospect, we knew it was not going to work. We allowed it to test the system."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

Credible and ethical behaviour related to GE trials execution and in particular the sweet potato field trial was also compromised as claimed by one molecular scientist from an academic institution, and confirmed by a molecular scientist from a civil society. Both argued that, requisite safety tests were not carried out to guide ethical regulatory decision-making process.<sup>136</sup> The academic scientist noted:

*"Personally I would not have taken that sweet potato to the field. They [responsible scientists] probably did not bother because there are basic things that you can do to tell you that this plant is bioengineered...I am just saying sometimes when you are a scientist you have to see it differently from the other people."* (RSAc-GP5, research scientist, public university, Dec. 2007)

While the civil society scientist interviewee remarked:

*"As a scientist I know we left ampicilin resistant genes and a few other very nasty genes which we should have removed before even releasing for a cow to eat."* (EPA-NSS5, environmental protection advocacy, civil society, Jan. 2008)

The regulatory instruments prior to the Biosafety Act are unclear about how credibility as an ethical practice is linked to compliance and monitoring. Further, compromises at early years of regulatory process can perhaps be linked to lack of clear regulations and guidelines to guide objective and ethical regulatory practice (see Chapter five, section 5.5). However, the Biosafety Act provides for intensive monitoring through designated biosafety experts (Articles 43 & 45).

### **6.2.2.3 Attitude towards regulations and regulators**

Many policy scientist interviewees described scientists as having a negative attitude towards regulations.<sup>137</sup>

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<sup>136</sup> Interviews with RSAc-GP5 and EPA-NSS5.

<sup>137</sup> Interviews with ATp-PS3, PRp-PS4, RSIn-PS6, RSIn-GP9, RSIn-GP2, RSPu-GP1 and RSPu-GP4.

*"The regulatory documents were very clear but strange enough nobody paid attention, and as usual for scientists, we are not used to these stringent regulations. All those regulations were set up by the scientists themselves but when it comes to application, they want to evade them, feeling it is like waste of time [implementing them]." (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)*

The reasons behind this negative attitude were explained in varying ways by both scientist and non scientist interviewees. Some attributed it to conflicting motivations like research interests discussed previously, making scientists view regulations as "*hindrance to science*" (LABp-NS8, Jan. 2008). A senior policy maker further observed:

*"As a breeder for example, all you want is your product to get to the market as soon as possible. And if there is anything to delay the process, then you take a short cut. We [regulators] are saying that with these [GE] products, taking shortcuts will not help them." (ARp-PS2, regulatory and policy advisor, MOA, Jan. 2008)*

Others explained that scientists find it difficult to adjust from their normative basic research behaviour to a supposedly demanding research practice like the one demanded by GE research. Others thought that, scientists are "*narrow minded*," have "*optimistic thinking*" and are proud; factors which nevertheless make them ignore regulations:<sup>138</sup>

*"In most cases we tend to think that science is more superior so you have that temptation of ignoring [regulations]...the pride of being scientists." (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)*

The attitude of researchers towards regulators and vice versa promoted suspicions and misunderstandings amongst them, constraining effective regulatory practice:

*"KARI scientists are suspicious of the regulators, that they are too much of a police than a guide. There has been a feeling that some of the regulators really just want to punish the scientists....the mistrust and the fact that at one time they worked together in an institution. There is that feeling that, now I am the boss, you cannot do this [GE research] without me." (TAN-NSS2, technology advocacy, international NGO, Jan. 2008)*

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<sup>138</sup> Interviews with, PRp-PS4, ARBp-PS16, BIp-PS1, ATp-PS3, ARp-PS2 and PRp-PS10.

Some linked this to personality issues. KEPHIS regulators and KARI scientists were perceived to be suspicious and at times undermining each other, which was attributed to the fact that most KEPHIS employees were previously KARI research scientists.<sup>139</sup>

### ***6.2.3 Poor public communication and biased reporting***

This section reports on practice of scientists related to how they disseminate research information emanating from the GE research trials. The regulatory instruments prior to the Biosafety Act and the Act itself are implicit about how this reporting process should be managed. They however emphasise on transparency that should promote public trust. RoK (1998) in particular recommends “openness” to “safeguard public interest” through transparent handling of information and adhering to NBC terms and conditions of trial approval (executive summary). In RoK (2009), NBA is wholly responsible for information handling and management including consequent public awareness. A register will also be maintained as a repository for biosafety information. It is however unclear how interested parties should access it. It is anticipated that details on how this should be managed will be inputted in the regulations being drafted to be appended to the Act. The supporting regulatory instrument (KEPHIS, 2004b) is explicit about reporting of undertakings during crop trials management but other non crops trials are not covered. In addition, this is not a legally binding instrument.

Accounts of interviewees suggest that scientists have poor communication skills on GE matters that are meant for the non-scientific community. In addition, when they communicate (as demanded by the sensitive nature of this technology), there are weaknesses that are revealed through the reports and the communication strategies they adopt. However, many interviewees were in agreement that scientists have a very important role to play in communicating scientific and technical facts to the public about their GE work. Some perceived this as the only way of demystifying the

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<sup>139</sup> Interviews with TAR-NSS1, ATBp-PS5, TAN-NSS2 and ATp-PS3.

prevailing negative publicity around GE technology. There were however perceived weaknesses and challenges in the articulation of this role which are explored next.

### 6.2.3.1 Communicating science versus public understanding of science

Some scientist interviewees claimed that research scientists use “scientific jargon” that need to be “toned down” for lay people to understand.<sup>140</sup> These sentiments were corroborated by many non-scientists who supported use of simple and unbiased language that laypeople can understand.<sup>141</sup> One non scientist noted:

*“From a non scientist’s point of view, the scientists have got to tell those of us who are not scientists what it is that they are doing. Scientists have to come out and find a non-scientific way of speaking to the public and make them see both the good and the bad side of GE science.”* (LABp-NS8, parliamentary counsel, Attorney General’s chambers, Jan. 2008)

The use of technical and scientific language was perceived to be an indicator of poor communication skills that purportedly differentiates pro-GE scientists from anti-GE activists.<sup>142</sup> One journalist emphasising this difference had the following to say:

*“Scientists talk scientific jargon such that you get so much lost as a journalist. On the other hand, an NGO activist will explain to you in a language you can understand...so it is reported in a very simple and distorted manner but that is what you understand. You tend to take as journalist what you understand. They [scientists] must learn communication skills.”* (JO-NS6, journalist, local daily, Apr. 2008)

This discussion seems to point out that scientists have not come to the level of the non scientists or the public when communicating technical aspects of GE research. This analysis does not however expose the reasons behind this seemingly uncomfortable behaviour and repercussions. This is the subject of the next subsections.

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<sup>140</sup> Interviews with RSPu-PS8 and TAN-NSS2.

<sup>141</sup> Interviews with LABp-NS8, TAI-NS10, NGOf-NS2, NGOf-NS1, JO-NS6 and NGOco-NS4.

<sup>142</sup> Interviews with JO-NS6 and JO-NS7.

### 6.2.3.2 Public communication constrained by fear of misinterpretation

Agreeing with the perceived poor communication claims, many GP interviewees and a number of NSS interviewees argued that they deliberately avoid communicating scientific findings to the public because of fear of misinterpretation, propaganda and potential negative impact this may have, for instance on their careers and research reputation. Debatably, protection of their careers and good reputation through upholding of good research ethos involves reporting undisputed “good research”.<sup>143</sup> One scientist emphasising this communication dilemma argued:

*“Scientists are not really public speakers, they fear being misquoted. We would like to tell the facts out there to the people, but the media always misquote us and we find ourselves in very awkward position. That is the constraint that the scientists are having in communicating science out there to the world and a lot of them fear because they don’t know what impact it may have on their jobs.”* (RSIn-GP3, research scientist, IRI, Mar. 2008)

Fear of propaganda was associated with activists, who some claimed unjustifiably fight GE technology impacting on scientists’ reporting behaviour, as one NSS interviewee explained:

*“So they [research scientists] have avoided bringing negative stories and even when they see them they remove them and instead keep quiet. The reason being the activists grab that and start using it as tool of propaganda to make people turn against GE. So why talk about the negatives if they are gonna bring you problems. Experience has shown that, any negative you bring will be used against you. So we have to continue in the way I think we are at least less risky.”* (TAR-NSS1, researcher & technology advocacy, international NGO, Feb. 2008)

A number of non scientists agreed with scientists that scientific facts can be misinterpreted in different contexts.<sup>144</sup> One journalist interpreting the tendency of scientists to refrain from reporting science for public use commented:

*“Historically I know that scientists have a tendency of keeping aloof. They fear that what they do [research] may be misreported.”* (JO-NS7, journalist, local daily, Mar. 2008)

<sup>143</sup> Interviews with TAN-NSS2, TAN-NSS4, ATBp-PS5, PRp-PS4, BIp-PS1, ARp-PS2, RSIn-PS6 and RSIn-GP3.

<sup>144</sup> Interviews with JO-NS7, NGOf-NS2, NGOco-NS5 and LABp-NS8.

This has implications as many scientists asserted. The fear of reporting non-factual and unverified or unconfirmed findings constrain effective and timely reporting, leaving room for misinterpretation by counter groups, as one policy interviewee noted:

*"We would like to go to the public with what we are certain about but at the time we are going there, somebody else has gone to say what we do not know. It now becomes very difficult to address an issue of what you do not know because in science it is basically search of the unknown. So when you know something is when you can talk about it. When you don't know you can't say much. But if someone is now saying this is what you are not telling us, yet you do not know it; it becomes very difficult to counter."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

Arguably from analysis of this section, scientists are held back from freely sharing their findings with the public by fear of repercussions associated with misinterpretations. This has implications for practice on the part of the scientists in respect of information and knowledge management, and how this is interpreted by others. These issues are reviewed in the next subsection.

### **6.2.3.3 Communicating the positives and transparency**

Many scientists admitted that when scientists communicate about GE science, it is basically the positive and promotional information that highlights benefits more than risks.<sup>145</sup> Misinterpretation was affecting the way scientists communicate, compelling them to talk more of tangible benefits and less on unverified or "*unknown*" risks.

Several non scientist interviewees corroborated the "biased reporting" linked to provision of information inclined more to successes.<sup>146</sup> One of them had the following to say:

*"In Kenya, all we are hearing are the positive aspects. We know that no technology in this world is without risks. So why is the potential risk side [of GE technology] silent? That in itself sends alarm bells to us [civil society]."* (NGOf-NS1, farmers' rights advocacy, civil society, Nov. 2007)

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<sup>145</sup> Interviews with RSIn-GP9, PRp-PS10, ARBp-PS16, ATBp-PS5, TAN-NSS2 and TAN-NSS4.

<sup>146</sup> Interviews with NGOf-NS1, NGOf-NS2, NGOf-NS4, JO-NS6 and JO-NS7.



Defending this practice, some researchers argued that, the nature of biological science training encourages them to pursue only facts, compelling them to withhold information that cannot be validated.<sup>147</sup> This was discussed in connection with confidence and easiness in reporting facts as opposed to unverifiable information like cases of uncertainty. They further argued that reporting on GE risks may cause panic among the public if negative non-validated aspects related to scientific “*process*” are highlighted.<sup>148</sup>

A policy scientist however claimed that, scientists withholding of some information was linked to “*a normative rigid research practice*” that compels them to vet what they report (ATp-PS3, Nov. 2007). This was corroborated by a journalist who portrayed scientists as research minded and rigid:

*“Most of them will be willing to give the information and share it with the media as long as things are going on well for them....he doesn't want to report failure. He is not looking at the possible aspect of the experiment changing its course along the way. To him, it is not an open ended research but a closed end research - get from here to there and if he is not getting there, then he is not doing what he is supposed to do. That is the way he looks at it. The moment things [findings] are not going on according to their [research] proposal, they will not discuss it.”* (JO-NS6, journalist, local daily, Apr. 2008)

This analysis seems to portray scientists as self centred, and tends to put to doubt their previous claims of fear of misinterpretation. Questionably, there is a disconnect between constrained communication and the unbalanced information consequently disseminated. These issues are explored briefly in the next section and revisited in the next chapter.

#### **6.2.3.4 Unreliable & biased information and multiple obligations**

Exogenous pressures were perceived by a number of scientists and most civil society interviewees to be limiting the reporting freedom of researchers, prompting them to

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<sup>147</sup> Interviews with RSPu-GP4 and RSPu-GP1.

<sup>148</sup> Interviews with RSIn-GP9, RSPu-GP4, RSPu-GP1, ARBp-PS16, TAR-NSS1 and TAN-NSS2.

produce what was referred to as “*biased*” and “*unreliable*” information, presumably manipulated to suit certain interests.<sup>149</sup>

Many felt that, reports emanating from trials were unreliable because of the partnerships environment under which GE trials are undertaken. This was perceived to be prompting reporting that favoured multiple obligations commensurate with different interests. For instance, a policy scientist interviewee commented that institutional expectations constrain the GE practitioners from reporting certain risk aspects that may be unacceptable to their employers’ developmental agenda:

*“Scientists might fail to report something [negative] because they know they will lose their job. Maybe the institute want to make a story out of it [out of the breakthrough]. They might be scared if they tell something bad about it. Sometimes scientists might be driven by different factors to take different [compromising] positions.”* (ARBp-PS16, research scientist & biosafety policy advisor, public university, Mar. 2008)

While another senior policy scientist describing the reporting pressure coming from donors remarked:

*“The donor has been very specific in the areas they would expect information from, such that the scientists sometimes are limited.”* (ARp-PS2, regulatory and policy advisor, MOA, Jan. 2008)

One civil society representative further noted: “*it is difficult to say per se that in the current [donor] context the information from those researchers would be fully reliable*” (NGOco-NS4, consumers’ network, Jan. 2008). Despite this scepticism, research scientists were perceived to be providing purportedly “*unreliable information*” related to trials management that is nevertheless supposed to guide further decision-making processes.<sup>150</sup> Referring to the mismanagement of the *Bt* maize trial case reported elsewhere and potential misinformation, one regulatory scientist noted:

*“How many of those types of mistakes are being committed and we could be making decisions based on wrong assessment not only without the knowledge of*

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<sup>149</sup> Interviews with ARp-PS2, PRp-PS4, EPA-NSS5, NGOf-NS2, NGOcs-NS3, JO-NS7, NGOco-NS4 and JO-NS6.

<sup>150</sup> Interviews with PRp-PS4, Blp-PS1, ARp-PS2 and TRTp-NSS3.

*the regulator and even the public who is being given the information?"* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

Perhaps partly explaining the unbalanced reporting cited in the preceding sections, the exogenous pressures and associated multiple obligations seemed to exacerbate the communication endeavours. These issues are discussed later in the next chapter in the light of their potential to impact the regulatory process.

#### ***6.2.4 Conclusion with respect to dynamics associated with scientific practice***

The preceding analysis suggests that certain technical and non technical factors largely influenced the behavioural practice exhibited by scientists in the implementation of regulations. Some factors are associated with opportunities presented by GE science, while others are linked to challenges that confront scientists as they engage in biotechnology research and regulatory process. Although the focus of this chapter is the role of scientists in shaping the regulatory process and instruments, the foregoing analysis provides a context for critical analysis of this role in the remaining part of the chapter and the subsequent chapters.

### **6.3 Scientists shaping of the regulatory process & instruments**

Efforts to develop a legal biosafety regulatory system have been running concurrently alongside the biotechnology activities. Developments related to the regulatory process have occurred in four distinct regulatory phases and role of scientists in shaping the process and the policy instruments is debated in this context (see Chapter two, section 2.4).

#### ***6.3.1 Scientists early role & behaviour at initiation of the regulatory regime***

Scientists played different roles at the early phases of the regulatory process but this occurred in a backdrop of cumulative learning and knowledge production.

### 6.3.1.1 Scientists as experts and advisors

*Undisputed early role:* Many interviewees were in agreement that the drafting of the first regulations and guidelines was wholly undertaken by scientists in research, academic and policy arena. RoK (1998) acknowledges the work of seven drafting committee taskforce members who are from academic, research and policy institutions. This scientists' early involvement in drafting and steering the regulatory process was not disputed because as argued by one member, they had the needed technical capacity to understand the purportedly technical and complex science:

*"The constitution of the first team that wrote the guidelines was predominantly scientists. It was historical in that capacity of other groups such as consumers and other groups was limited in understanding the science behind the development of biotechnology." (ATBp-PS5, technological & biosafety policy advisor, public university, Nov. 2007)*

KARI research scientists were instrumental in shaping the Kenyan regulatory process and were widely mentioned by both scientist and non scientist interviewees as having pushed for the drafting of the first regulations and guidelines.<sup>151</sup> Some interviewees supported this role claiming that KARI scientists were key stakeholders in the regulatory framework development.<sup>152</sup>

KARI's role actually revolutionized the government operations and priorities.<sup>153</sup> The National Council for Science and Technology (NCST) actually shifted its focus from general science and technology to the establishment of a regulatory regime in order to support GE research (Sander, 2007). A GP interviewee explained how this occurred:

*"If there was no KARI or research institution trying to push, the priorities of NCST would have been different because their work is not exclusively GMOs. What they [KARI scientists] were doing created need for regulations to be developed. It was a need-based initiative. KARI as a research institute was vital in defining the priorities of NCST with regards to GM research." (RSIn-GP9, research scientist, international intermediary organisation, Nov. 2007)*

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<sup>151</sup> Interviews with ABp-PS14, BIp-PS11, ATBp-PS5, TAN-NSS4, FSp-PS12 and LABp-NS8.

<sup>152</sup> Interviews with RSPu-PS7, RSPu-PS8, FSp-PS12 and LABp-NS8.

<sup>153</sup> Interviews with RSIn-GP9, TAR-NSS1, BIp-PS11, RSPu-PS7, RSPu-PS8, ATBp-PS5 and PRp-PS4.

Confirming this early active role, one non-scientist commented: *"the 1998 regulations were developed by scientists for scientists without considering the other wider stakeholder users."* (LABp-NS8, Jan. 2008)

**Coordination and advisory role of policy scientists:** Two key policy scientists interviewed in this study claimed that they were relied upon extensively to advise the Ministry of Agriculture and regulatory agencies on both biotechnology and regulatory issues. Consequently, this advisory role impacted upon the regulatory process trajectory.<sup>154</sup>

### 6.3.1.2 Incremental learning influencing the regulatory trajectory

In the process of drafting the biosafety regulations, there was an element of learning which enhanced the process. Much of the early learning was supported by donors who built awareness amongst the scientists involved in drafting the first regulations and the policy figures involved in implementing the drafting process.<sup>155</sup> For example one policy actor noted that a regional biosafety workshop held in Harare, Zimbabwe prior to drafting of the regulations was an eye opener to the Kenyan scientific community who attended this workshop with regards to the need for biosafety regulations:

*"Way back in 1992/1993 KARI had received an application for a trial, so when they came to the Council, they asked to be advised on regulations and advise on what to do. I could not understand about the regulations because we only knew about the research permits. It so happened that around 1993/1994, I was invited for a workshop in Zimbabwe attended by 11 persons from Kenya. When we were now discussing what this biotechnology is all about, I came to understand why we needed the regulations and straight away I was nominated the chairman of the Kenyan group to spearhead that activity right there. When I came back to Kenya I was very aggressive and I started to constitute groups to discuss the kind of applications that KARI had submitted. We drafted the first draft, and finally we came up with the regulations."* (BIP-PS11, policy advisor, government agency, Feb. 2008)

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<sup>154</sup> Interviews with RSPu-PS7 and PRp-PS4.

<sup>155</sup> Interviews with BIP-PS11, TAN-NSS4 and ATBp-PS5; see also Sander (2007).

After the workshop referred to here, a taskforce was formed in 1995 comprising of natural scientists (most of them having been sensitized during this workshop) and one legal expert to spearhead the drafting of the first regulations that were officially launched in 1998 (Thitai *et al.*, 1998). This scientific task force also determined the early constitution of the NBC members.

Subsequent learning obtained through familiarity with biotechnology and biosafety matters occurred during the execution of the research trials. Consequently, upon realisation of the regulations inadequacies during implementation, research scientists took up the active role of pushing for the review of the first draft.<sup>156</sup> Confirming this pioneering regulations review initiative, a regulatory scientist and a member of NBC noted:

*"Indeed it was the [research] scientists who pushed for the revision of the application form. It is better if you get the revision requirement from the users than when it is proposed by the NBC. They are the ones who discovered that some of this risk assessment information is required [in decision-making process]." (PRp-PS10, regulator, phytosanitary regulatory agency, Jan. 2008)*

Research scientists extensively contributed to both policy and technical learning through biotechnology and biosafety capacity building efforts that targeted policy makers and implementing scientists. These efforts were enhanced through the various research projects that they were involved in. This was aimed at influencing decision-making processes pertaining to various GE projects regulatory approvals and implementation:<sup>157</sup>

*"Kenya like all other countries makes institutions, and then employs people trained in just general education, and then they are supposed to regulate very scientific work. So it was very important to expose them to the technology itself and expose them to other institutions that are practicing it to understand how it is [regulated]." (RSIn-GP2, research scientist, IRI, Dec. 2007)*

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<sup>156</sup> Interviews with RSIn-GP9, PRp-PS4, BIp-PS1, PRp-PS10 and TAN-NSS4.

<sup>157</sup> Interviews with RSIn-GP9, RSPu-GP4, RSIn-GP2 and RSPu-GP1.

A senior policy scientist confirmed how he was sensitised on biosafety regulation through efforts initiated by research scientists:

*"I was exposed to the biosafety regulatory environment through the scientists' interest at Michigan State University. The scientists drove the early regulatory process."* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

The opportunity presented by biotechnology science seems to have also demanded requisite learning towards technical understanding, and engaging with both the technology and biosafety. This partly explains the reasons why the two co-evolved since as presented in this section the majority of actors embraced learning and supported efforts like capacity building to sustain the co-evolution approach.

#### **6.3.1.3 Conclusion with respect to early role & introducing next section**

The roles played by the scientists at this stage directed the regulatory process without any contestation. Different interpretations may be drawn from this (see Chapter seven). The increased learning provides a context for, perhaps the positions scientists occupy and the role they play in the subsequent regulatory phases as an informed group with regards to familiarity with technological and biosafety aspects.

Despite the availability of scientific knowledge and institutions which seemed to support technology deployment (e.g. research, government, donors, NGOs, NBC and IBCs), what is not very clear from the analysis of this early role is the actors' motivation, and how learning was harnessed and sustained to spur significant policy change. The situation seems to suddenly change in the subsequent regulatory phases as actors engage in diverse roles and activities towards legalisation of the regulatory process and instruments. The important point to note that leads us to the next section is the radical change in the conceptualisation of the regulatory process and instruments by both the scientists and non scientists.

### **6.3.2 Role & behaviour of scientists in the legalising of regulatory process & instruments**

National efforts to establish a legally binding regulatory regime in compliance with Cartagena Protocol commenced in Phase 2 of the regulatory process. Many interviewees argued that biosafety regulations formulation process engaged the scientific community in various ways which indicates shaping of the regulatory process in terms of direction and content. In this section, these activities and developments that relate to formulation of regulations particularly the Biosafety Act 2009 are discussed, while implications are explored at the end of the section.

#### **6.3.2.1 Activism of scientists masking government role**

The National Council for Science and Technology (NCST) coordination role in drafting of the first regulations to govern modern biotechnology activities was pivotal and undisputed. Consequently, RoK (1998) as a regulatory instrument provided for an institutional framework for regulatory process but under the coordination of the NCST and the National Biosafety Committee (NBC). One of the roles of the NBC according to RoK (1998) was to draw policies and procedures to govern biotechnology. In this regard, this gave NBC through the NCST the legal powers to spearhead the policy-making process. However, NBC coordination role in the biosafety bill formulation process was perceived to be blurred by the activism of other actors, a view shared by both scientists and non scientists.<sup>158</sup>

*“It is difficult to know who has been driving this [bill] process but I think the NBC should be playing a bigger role.”* (RSIn-GP3, research scientist, IRI, Mar. 2008)

Arguably, the scientists and their allies became the main drivers of the bill formulation process. A non-scientist interviewee confirming this role argued:

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<sup>158</sup> Interviews with RSIn-GP3, RSPu-GP1, RSPo-GP6, PRp-PS10, FSp-PS12, ARp-PS9, JO-NS6 and NGO-NS2.



*"The main players were the biotechnology industry, and the scientists make much of the industry. The whole thing [bill formulation process] was supposed to be an initiative of the NCST but the interest was with people from the biotechnology industry than what we would call the broader section of Kenyan society." (JO-NS6, journalist, local daily, Apr. 2008)*

The regulatory instruments however do not state how this process should be advanced and how stakeholders should be engaged. This seemed to leave room for different styles of actors' engagement in formulation process, and perhaps the reason why the role of the government could be masked easily.

NBC is also largely made up of scientists representing different organisations with two representatives from the civil society. This being the case, and with lack of clear guidelines on how the process should be directed, it can be concluded that scientists and their affiliated institutions seized this opportunity to influence the process as interested parties. Without losing hindsight of the learning and familiarity that had since occurred, the next section turns to how scientists engaged in the formulation of the biosafety bill and related tensions.

#### **6.3.2.2 Technical backstopping of regulatory process & conflict of interests**

Many interviewees perceived the research scientists to have technically backstopped the regulatory process.<sup>159</sup> Some of them however argued that, this was a positive influence which was necessary to ensure a balanced and a scientific process through provision of technical information:

*"The bill was drafted by legal experts guided by scientists. The ideas came from scientists. They set up a framework that ensures decisions that are made are based on real scientific facts." (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)*

However, this technical support was questioned extensively by some interviewees. Some observed that scientists are driven by research interests and thus their

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<sup>159</sup> Interviews with PRp-PS10, PRp-PS4, RSIn-PS6, ATp-PS3, ATBp-PS5, ARp-PS9 and BIp-PS1.

participation in the regulatory policy process is to push for policies that would promote biotechnology science.<sup>160</sup> A NSS interviewee confirming this research driven push and reason behind it commented:

*"You find that the scientists have been putting a lot of pressure already. They have been doing these things [research], then there are no regulations and procedures to use....the government arms should be way ahead and not wait until the scientists are caught up with the technology and then you don't know what to do with these scientists." (TRTp-NSS3, research & trade policy advisor, association of seed traders, Nov. 2007)*

This is perhaps the reason why some emphasised that any scientific contribution to the regulatory process needed to be vetted by the public to ensure balance with non-scientific aspects.<sup>161</sup>

*"Whatever they put down, it needed to receive a consultative process to receive views from different stakeholders to question the content. There is a danger if it gets to be overwhelmingly driven by scientists, [and] then they will structure it just to address scientific needs. Science is for the benefit of the society and society must view it from that light." (RSIn-GP9, research scientist, international intermediary organisation, Nov. 2007)*

Admitting that this nature of influence actually occurred, a GP interviewee involved in the bill formulation explained:

*"I could also look at how the bill would affect the scientists who want to do biotechnology research in the country.....so I have also to think about how this [bill] can affect the scientists in future." (RSPu-GP1, research scientist, PRI, Jan. 2008)*

Scientists sitting at the NBC are also perceived to be interested parties as applicants or potential applicants, and are likely to influence decisions to favour interests of scientists through the biased technical information they provide for risk assessment (RA).<sup>162</sup> One scientist and an NBC member commented:

*"If the information you are trying to regulate on is coming from the people you are trying to regulate, then definitely they will frame it in a way that make their applications to always to go through [get a regulatory approval]. They will skew*

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<sup>160</sup> Interviews with RSPu-PS8, RSPu-GP1, RSIn-GP2 and RSIn-GP9.

<sup>161</sup> Interviews with RSIn-GP9, TAD-NSS6, NGOf-NS2, LABp-NS8 and NGOf-NS1.

<sup>162</sup> Interviews with RSIn-PS6, ARBp-PS16 and RSIn-GP3.

*it such that even them when they make an application, it will go through.”*  
(RSIn-PS6, general health & safety advisor, IRI, Nov. 2007)

Exogenous and endogenous pressures and related interests discussed previously further constrained scientists from exercising objectivity in various regulatory undertakings. Many interviewees reported that scientists have been used as conduit to advance interests of pro-biotechnology organisations or to achieve national technological development agenda.<sup>163</sup> A civil society interviewee, explaining how in practice pro-biotechnology organisations influence the thinking of players in the regulatory process noted:

*“The people at the NBC are the people who are always taken to USA under the Cochran fellowship. They go to see those big farms that are producing GMOs; they are given very good per diems. When they come back, their thinking has already been manoeuvred.”* (NGOcs-NS3, civil society’s rights advocacy, environmental NGO, Jan. 2008)

Moreover, it was a concern of non-scientists from the civil society that technical information used in RA and consequent decision making pertaining to GE trials was solicited by scientists from technology developers who are interested parties.<sup>164</sup>

Despite the potential conflict of interests, scientists were perceived to be key players in regulatory process as facilitators, and through their active involvement provided a regulatory mechanism through which NBC and IBC could operate.<sup>165</sup> One PS interviewee in support of the purportedly positive influence had this to say:

*“The scientists never drove the process, they were just the initiators. They are the ones who woke us [NBC] up to want to have those regulations in place.”*  
(ARBp-PS16, research scientist & biosafety policy advisor, public university, Mar. 2008)

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<sup>163</sup> Interviews with ARBp-PS16, ATBp-PS5, RSPu-GP1, EPA-NSS5, PRp-PS4, RSPu-PS7, TAI-NS10, NGOof-NS1 and NGOcs-NS3.

<sup>164</sup> Interviews with NGOof-NS1, NGOco-NS4, NGOco-NS5, NGOof-NS2 and NGOcs-NS3.

<sup>165</sup> Interviews with ARBp-PS16, ATBp-PS5, RSIn-GP9, BIp-PS11, TAN-NSS4 and PRp-PS4.

Despite the conflict of interests and the arguments for or against the nature of influence, role of scientists in the bill formulation process was articulated in different ways, discussed next.

### **6.3.2.3 Institutionalised influence of biosafety bill**

As discussed in Chapter two, there are many actors involved in the evolution of both modern biotechnology and the biosafety regulatory regime. This co-evolution scenario seemed to provide a conducive environment for the scientific community to pursue their motivations and interests in an integrated way. Thus, activities related to influence of the regulatory process were articulated within or through institutional nodes and knowledge networks. From the preceding section, data suggest that scientists impacted regulatory policy process as regulatory experts and whichever role they played to shape the regulatory process is perceived to have received blessings from the government side.<sup>166</sup> Interestingly, the government side is also comprised of scientist actors who have moved from public institutions to become policy makers which may further bring about conflict of interests (see Appendix 1).

The nature and role of the ensuing relationships formed around the formulation of regulatory instruments, particularly the bill, were consequently interpreted in different ways as collaborations, facilitation or activism, spurred by different factors. The nature and forms of these relationships together with the related influence are discussed next.

#### **1. Scientists working within institutions and networks**

A number of key professional and knowledge based networks within which scientific and non scientific communities influenced the regulatory process were identified in data analysis as follows:

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<sup>166</sup> Interviews with JO-NS6 and JO-NS7.

*The Open Forum on Agricultural Biotechnology in Africa (OFAB):* At the height of debate on regulatory policies (biosafety bill) in Kenya in 2006, OFAB as an early initiative of ISAAA and AATF was launched. Its formation was claimed to have been motivated by the regional High-Level African Panel on modern biotechnology set up by the AU to advise African heads of states on biotechnology and therefore appropriate policies to support it (Juma and Serageldin, 2007). OFAB was to address the country level (Kenyan chapter) as there was perceived need for “national scientists and experts to provide policy makers and the general public with evidence needed to harness such technologies” (see [www.ofabafrika.org/country](http://www.ofabafrika.org/country)).

It has two main objectives: First, to popularise biotechnology:

*“OFAB is a place where scientists meet and share their views on cutting-edge science, research and development issues”* (some senior scientists at CIMMYT, quoted in Karembu *et al.*, 2008).

Second, to push for conducive policies to enhance technology transfer:

*“Through the forum, the scientists get the much needed chance to impact policy makers on the need to mainstream science and technology into Africa’s development agenda.”* (Karembu *et al.*, 2008:12)

Indeed the promotion of biotechnology and development of permissive regulatory instruments have been major items of debate during over 24 OFAB meetings held in about two years (Karembu *et al.*, 2008 and [www.ofabafrika.org/country](http://www.ofabafrika.org/country)).

The committee members of OFAB, Kenya chapter, comprise 6 scientists and 2 non-scientists drawn from AATF and ISAAA as the secretariat. The chapter is chaired by a non state organisation-ISAAA. In contrast, the OFAB Uganda chapter initiated by the same Kenyan actors is chaired by the Uganda government through the Uganda NCST and the Government public research institute, the National Agricultural Research Organisation (NARO) (see [www.ofabafrika.org](http://www.ofabafrika.org)).

**The Kenya Biosafety Consortium (KBC):** was formed in 2006, where members were predominantly pro-biotechnology scientists, with support from government through NCST, united under one agenda; having a biosafety law to pave the way for biotechnology deployment:<sup>167</sup>

*“We got together as different stakeholder in the biotechnology arena in Kenya and formed what we called the Kenya Biosafety Consortium.....then ISAAA was charged with the responsibility of helping with the coordination of the consortium. We all agreed that one of the major milestones that we can make in this country if we really have to move with the technology is to have the biosafety law.”* (TAN-NSS2, technology advocacy, international NGO, Jan. 2008)

Its operations were strategic and political in nature as insinuated by one policy interviewee:

*“You are a scientist but you have to understand the society. That Biosafety Consortium was a pressure group to strategize how the biosafety bill would be discussed and go through. It has hibernated because now there is no biosafety bill anywhere. But immediately we start the process, they might come out again as Biosafety Consortium or maybe another name.”* (BIp-PS1, biosafety policy advisor, government agency, Jan. 2008)

A point to note is that activities of this consortium ceased after the bill was enacted into law.

**The National Biotechnology Awareness Strategy (BioAWARE):** is a public awareness initiative that was conceived by the scientific community and articulated through the Agricultural Sector Coordinating Unit (ASCU) within the Ministry of Agriculture (RoK, 2008b). This initiative was launched in 2008 and a key participant (not involved in the drafting though) was the Kenya Federation of Agricultural Producers (KENFAP, previously Kenya National Farmers Union). KENFAP was identified as a key player in reaching out the farmers while the Ministry of Agriculture has an established extension

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<sup>167</sup> Interview with TAN-NSS2 and analysis of the minutes of several meetings held by this consortium.

service.<sup>168</sup> Something to note is that the chairman of this initiative is a scientist and also an executive member of OFAB. This may perhaps explain how important partnering and collaboration had become to scientists in ensuring that they achieve their goals, including public awareness.

These partnering initiatives may imply that the Kenyan scientific community cannot be perceived to be non-partisan and disinterested players in the biotechnology arena and biosafety regulatory process.

## **ii. Mutual and resource bound relationships**

The relationships established around the regulatory process in the Kenyan context were mutual in that the participating players expected to benefit. Scientists and the government were on the one hand receiving financial support from non state actors. For instance, GP scientists are pursuing biotechnology research projects under Public Private Partnerships (PPPs) which some scientist interviewees interpreted as government policy support for GE deployment.<sup>169</sup> On the other hand, the non state actors have received political and scientific support to advance their interests in different ways. Some NSS and non scientist interviewees from the biotechnology industry interviewed in this study admitted to have been articulating facilitation roles in the policy process indirectly through their scientist partners, arguing that direct involvement would elicit negative suspicion, citing sensitivity of GMOs.<sup>170</sup> One industry interviewee explained his company's motivation for engaging in regulatory process through relationships established locally:

*"If we get too involved, then of course as an interested party it will raise a lot of eyebrows and create a lot of resistance against us and our products. So we tend to support those who have a national interest - the research community and*

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<sup>168</sup> This analysis is supported by recorded speeches of the chief executive of KENFAP, the minister for agriculture and the director of agriculture during the launch that I attended in Sep. 2008 in Nairobi, Kenya.

<sup>169</sup> Interviews with RSPu-GP1, BIp-PS1 and BIp-PS13.

<sup>170</sup> Interviews with TAD-NSS6, TAN-NSS2 and TAI-NS10.

*NGOs that are there to push for the farmers' interest. We work with them and through them. I am honest about this, the reason why we are still engaged in trials in Kenya is because we have seen fantastic collaboration from the scientists, very good science, very good reports and it is impossible to turn back. We have very good partners who are doing great science, are positive and who are influencing the policy debate. It is about relationships.”* (TAI-NS10, technology advocacy, biotechnology industry, Jan. 2008)

Meanwhile, another NSS interviewee noted how her donor organisation in addition to funding GE research facilitated eminent scientists to influence the bill through reaching out to policy makers, regulators and media:

*“We have supported scientists doing research, but we have also facilitated scientists to have the outreach to the Ministry of Science and Technology, who were looking at how the content of the biosafety bill could be shortened to ensure it is accurate... ensuring that it facilitates trade, facilitate research and commercialization.”* (TAD-NSS6, technology advocacy, donor agency, Feb. 2008)

Some NSS interviewees explained that they created partnerships and relationships to achieve what they consider to be product deployment.<sup>171</sup> The only NSS interviewee from the civil society, perhaps confirming these mutual and interest-bound relationships argued that scientists and their partners created a need for regulations, in order to promote GE products:

*“You can't create something from nowhere. Working with a big corporate, we tried to push these things [GE products] to Kenya and that would force them [the government] to work on the biosafety bill, policy regulations and all that.”* (EPA-NSS5, environmental protection advocacy, civil society, Jan. 2008)

These relationships and partnerships were perceived by many interviewees to have positively enhanced the regulatory process, with some arguing that private partners permitted the requisite space and freedom for the scientists to dictate the regulatory policy path.<sup>172</sup> Further, some of them were in agreement that the government has inadequate capacity to support the regulatory process, so these other supporting parties were filling in that gap. In support of this argument, a GP interviewee remarked:

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<sup>171</sup> Interviews with TAR-NSS1 and TAN-NSS2.

<sup>172</sup> Interviews with BIp-PS11, BIp-PS1, RSPu-GP4, RSPu-GP1, PRp-PS10, RSIn-GP3 and ATp-PS3.



*"When we do not have the capacity in Kenya we rely on others. At the moment the capacity lies with some of these international players and what they contribute ends up getting into the biosafety bill. So we really do need to develop the capacity for Kenyans to participate effectively in issues of biotechnology and biosafety."* (RSIn-GP3, research scientist, IRI, Mar. 2008)

The GP interviewees had their own perceptions of partners from non-state organisations. They admitted that they play key roles in GE research and the regulatory process, a role the government is not articulating effectively.<sup>173</sup> For instance one GP interviewee perceives some pro-biotechnology NGOs to be providing information on GE technology and the much needed financial support for regulatory policy development:

*"Being NGOs activists or brokers, they also have a stake because they are the ones who looked for the money and sometimes they are part and parcel of sometimes the research aspects. Like now, every OFAB meeting we have to pay for lunches and hall. The BioAWARE initiative someone had to sponsor it. I sponsored a number of days, Ministry of agriculture, but Dr. P from NGO Z sponsored more days than any of us. So she has more influence because she is the one who is able to contribute more."* (RSPu-GP1, research scientist, PRI, Jan. 2008)

From these accounts, resources and in particular financial support was a key incentive cementing these relationships. Indeed, activities and operations of the Kenya Biosafety Coalition (that played a key role in lobbying for the enactment of the bill) were funded by non state scientists through the pro-biotechnology organisations (BIp-PS1, Jan. 2008).

### **iii. Scientists collaboratively lobbying for enactment of the bill**

Many interviewees desired a regulatory environment that would enhance deployment of products of GE science. Biosafety bill was a gateway towards achieving that goal. There was resistance from opponents experienced along the way (see Chapter 5, section 5.6.1). To counter this, scientists in policy, academic and research arena supported by their affiliated organisations came together to push for the enactment of the bill.

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<sup>173</sup> Interviews with RSPu-GP4, RSAC-GP5, RSIn-GP3 and RSPu-GP1.

Under the umbrella of the Biosafety Consortium, the scientific community, with support from the government actively lobbied for the enactment of the bill as described by one policy interviewee who represented the government side in the consortium:

*"They [consortium members] were some institutions, those who had an interest in biotechnology which came together and decided to push the policy makers and the regulators. They were like brokers for the biosafety bill. I became a member because they wanted to hear the thinking of the Government for they thought the Ministry was the one delaying the process. So I was there to update them on the bill process [from government side]. I have called them a broker. So these people were between the executive and the parliamentarians. They were meeting the parliamentarians, they call me to tell me what they are saying, I ring the Minister....In fact it was a very good effort which was put together and we almost won the gold...and I am quite happy about them."* (BIP-PS1, biosafety policy advisor, government agency, Jan. 2008)

Some NSS interviewees interviewed in this study admitted playing an active role through the consortium as one noted: *"it is true we were quite involved in catalyzing the enactment of the biosafety bill"* (TAN-NSS2, Jan. 2008).

Media reports analysed during field work confirm some activism by the scientific community and government in support of the biosafety bill.<sup>174</sup> This was not received well by civil society who under the umbrella of the Kenya Biodiversity Coalition (KBioC) (previously KEGCO) responded proactively by discrediting the bill.<sup>175</sup>

#### **iv. Scientists corporately sensitizing key players as a persuasion strategy**

Scientists collectively educated policy makers and journalists, sensitizing them on GE thus making *"a case for biotechnology"* as well as persuading them to support it (RSIn-GP2, Dec. 2007). Sensitising public on GE technology is a role that all GE scientists are expected to be playing under OFAB.<sup>176</sup> Policy makers particularly parliamentarians were targeted in order to convince them in supporting and passing the bill in

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<sup>174</sup> Scientists in the academic circles publicly supported the bill, while the government through the NBC attempted to counter the negative publicity by civil society [see Appendix 9 and NCST (2007) in support of this argument].

<sup>175</sup> They published a parallel bill titled "the biotechnology and biosafety bill, 2008" and a comparative analysis of the two parallel bills. See also the article "biosafety bill 2008, Kenyan MPs selling the country" published in the Daily Nation on 25 Nov 2008 (Appendix 9).

<sup>176</sup> Interview with RSIn-GP3; [www.ofabafrica.org](http://www.ofabafrica.org); personal communication with scientists during OFAB forums that coincided with the field work (Oct 2007-March 2008).

parliament,<sup>177</sup> One policy scientist supporting this endeavour argued: “...parliamentarians [often don’t] go to parliament to talk of a technology which they have no idea about” (Bip-PS1, Jan. 2008). Journalists were targeted to enhance responsible reporting as argued by one GE practitioner:

*“The most dangerous group was the journalists. They had the means to give wrong information....We as scientists we have done a lot in educating the journalists. Today we see very responsible reporting in the newspapers.”* (RSPu-GP4, research scientist, PRI, Nov. 2007)

In an effort to educate and sensitise policy makers on GMOs, a Handbook for Policy Makers was published in 2007.<sup>178</sup> This manuscript has acknowledged contribution of technical content by various persons who are all scientists. This may imply that the handbook presents only scientific views. Another notable effort by the non state actors in sensitising the policy makers has been through the PBS/IFPRI-ISAAA program.<sup>179</sup> In one of the PBS publication, the following is stated:

*“PBS helped prepare the Kenya biosafety bill for enactment by educating members of parliament and preparing briefing documents for policy makers and media.”* (PBS Newsletter: Issue No. 13. [www.ifpri.org](http://www.ifpri.org))

Recently, the scientific community and other actors in the biotechnology arena have intensified promotion of biotechnology through the media alongside calls for policy support to achieve this goal.<sup>180</sup> Despite the undisputed and proactive efforts to change the thinking of certain players regarding biotechnology, some scientist and non scientist interviewees were concerned that these efforts had a hidden motive.<sup>181</sup> Some argued that the interested parties who included the industry were effectively pushing for regulatory

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<sup>177</sup> Interviews with RSPu-GP4, Bip-PS1, TAN-NSS2, TAR-NSS1 and RSPu-GP8.

<sup>178</sup> The handbook is published by ISAAA and gives an overview of the status of biotechnology in Kenya. It emphasises on the benefits of different applications of crop biotechnology & highlights the institutional and human capacity that exists to harness and consequently adopt biotechnology products. It concludes by recommending that the biosafety bill need to be enacted by the readers (policy makers) in order to tap the benefits of biotechnology.

<sup>179</sup> Through this program a number of policy documents have been produced: “*the truth about the biosafety bill*”; “*GMOs and exports: demystifying concerns in Africa*”. One of the achievements of this program has been listed as sensitising the policy makers ([www.ifpri.org](http://www.ifpri.org)).

<sup>180</sup> For instance a recent media report claims that pro-biotechnology reports have increased, fronted by scientific organisations and funded by biotechnology industry (East African daily of 26 May-1 June, 2008); The ISAAA publication, the Crop Biotechnology update, has been highlighting policy developments in Kenya and in particular developments surrounding the biosafety bill ([www.isaaa.org/kc](http://www.isaaa.org/kc)).

<sup>181</sup> Interviews with RSPo-GP6, RSPu-GP7, NGOco-NS4, NGOf-NS1, NGOf-NS2 and NGOcs-NS3.

instruments that are permissive in nature. One concerned non government regional expert and scientist remarked:

*“Our impression was that you had some lobbyists and they were pushing very hard with the Science Council [NCST]. Their agenda was to convince the politicians so that they can give them the go ahead [for their products]. So the target for those lobbyists was not science but members of parliament. So no attention was given to places like [regional organisation B].”* (RSPo-GP6, biomedical research scientist, regional pro-biotechnology organisation, Mar. 2008)

While a non scientist from the civil society complained:

*“If they [scientists and government] have nothing really to hide, why choose just a section of the members of parliament, fifteen of them, majority from Eastern Ukambani?”* (NGOf-NS2, farmers’ rights advocacy, Nov. 2007)

Others non scientists (contrasting the views of civil society interviewees) felt that the sensitisation role was geared towards lobbying for the enactment of the bill but did not see any hidden agenda in doing this.<sup>182</sup> Journalists interviewed in this study admitted receiving sensitisation training on biotechnology through the non state scientists both locally and abroad. They further admitted to have worked with the GP scientists with an objective of ensuring informed scientific reporting on GE technology. They perceived this to be a positive influence in terms of changing the negative perception of GMOs advanced through the media, towards informed and positive reporting.<sup>183</sup>

#### **v. Scientists adopting a “seeing is believing” as a tool for persuasion**

“Seeing is believing” is a concept extensively used by many interviewees, both scientists and non scientists.<sup>184</sup> The research scientists in collaboration with the policy scientists, non state scientists and industry confirmed that they devised a strategy to have the policy makers visit the biotechnology facilities, particularly the open field trials locally and abroad:

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<sup>182</sup> Interviews with TAD-NS11, LABp-NS8, JO-NS6 and TAI-NS10.

<sup>183</sup> Interviews with JO-NS6 and JO-NS7.

<sup>184</sup> Interviews with TAN-NSS2, BIp-PS1, RSPu-GP4, RSIn-GP2, TAR-NSS1, RSPu-GP8, RSPu-GP1, ABp-PS14, LABp-NS8 and TAI-NS10.

*"We organized for tours with other stakeholders so that policy makers can appreciate the facilities and preparedness that we have as a country to manage and contain this technology." (ABp-PS14, technological & biosafety policy advisor, MOA, Feb. 2008)*

Many of these interviewees perceived this as a way of convincing policy makers to identify with real evidence of GE potential locally and abroad. This way, they were bound to debate positively in parliament (from an informed point of view) after being persuaded and convinced concerning GE technology. One practitioner commented:

*"These outside trips have mainly involved the policy makers particularly the parliamentarians because these are the people who can move the biosafety bill in parliament. They had to be convinced first." (RSPu-GP8, research scientist, PRI, Dec. 2007)*

One non scientist supporting this approach perceived it to be positive influence:

*"Going to the site is good exposure...They may appreciate what they see in a different way. I do not think it is any form of bribery" (LABp-NS8, parliamentary counsel, Attorney General's chambers, Jan. 2008).*

In contrast, other non scientists from civil society linked this strategy to negative influence citing potential manipulation of policy makers' thinking, to favour interests of certain players.

#### **6.3.2.4 Conclusion with respect to scientists role in legalising the regulatory regime**

Biosafety formulation process as a pertinent step in legalising the regulatory regime engaged the scientific community intensely, using persuasive strategies in an integrated way. This was however viewed with suspicion by some interviewees, who were concerned with what they viewed as biotechnology promotional agenda and associated politics. A non scientist argued that the nature of activism portrayed by the scientific community in pushing for the enactment of the bill mirrored that of anti-GMOs activists (JO-NS7, journalist, Mar. 2008). Several documents obtained during field work and

personal observations during some of the scientific forums that I participated in during field work seem to confirm this pro-activeness.<sup>185</sup>

The analysis of the empirical data presented in this subsection suggests that policy related learning occurred at various nodes, among and across individuals but more importantly within strategic relationships. Evidence presented here further suggests that, knowledge produced at these diverse knowledge nodes influenced the regulatory process. It is however not clear from this conclusion whether the regulatory instruments in terms of content and the outcome of decision-making processes were influenced in the process. This is investigated in the next section. This way, the distinction between influence of the regulatory process and influence of output of the process is clarified.

### ***6.3.3 Influence: safeguards and control checks***

There seems to be strong evidence presented in the foregoing analysis that the scientific community had an influence on the regulatory trajectory. There were however different interpretations as to whether this impacted the final content of the regulatory instruments or particular outcomes of the NBC regulatory decisions.

Some interviewees explicitly described how the interests of scientists were inputted during the drafting of the first regulations whereby the content made provisions for scientists' subsequent ownership of the biosafety implementation process.<sup>186</sup>

A number of interviewees reported cases of attempts by scientist actors to influence the regulatory outcome.<sup>187</sup> One of them remarked:

*"We still have the challenge of people [applicants, scientists] trying to go lobbying, looking for who would be influential" (PRp-PS10, regulator, phytosanitary regulatory agency, Jan. 2008).*

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<sup>185</sup> The minutes of Biosafety Consortium (BC) and OFAB meetings. During the BC meetings, the subject of discussion was the flopped biosafety bill and revived strategies to engage the new members of parliament while addressing the shortcomings of the previous persuasion strategies.

<sup>186</sup> Interviews with ATBp-PS5, RSIn-GP2, ARp-PS2 and TAI-NS10.

<sup>187</sup> Interviews with RSPu-GP1, PRp-PS4, TAD-NSS6, TAR-NSS1, ARp-PS2, PRp-PS10 and ATp-PS3.

Meanwhile, another policy scientist explained how the pro-GE scientists tried to influence some content of the bill to suit their interests:

*“Some people wanted the number of days that the NBC or the proposed authority takes to make a decision to be reduced from 270 days to 90 days. This even went up to members of parliament committee who had almost been convinced.”*(ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)

Despite cited attempts to influence the regulatory process, many interviewees were optimistic that influence of the outcome of the process was unlikely. One senior policy interviewee made the following remark to support this view:

*“There was an attempt to try and influence how we would think about certain things. I do not believe they [biotechnology proponents] have influenced the regulatory environment otherwise by now we are supposed to have done things that really should not be done. They had the interest of getting certain things through which they have not gotten. It is true they have spent significant resources to try and get the regulatory process moving but they have not influenced the content of the final product. They may have influenced the thinking in delivering the final product. If they had any influence; the draft bill would be completely different and even the policy.”* (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)

Different explanations were provided by interviewees to show how influence of outcome was minimised through safeguards and control checks. These are explored next thematically.

#### **6.3.3.1 Credibility of scientists and capacity**

Many interviewees felt that, credibility of scientists curtailed any attempt by interested players to use them to influence the final regulatory output.<sup>188</sup> A regulatory scientist noted: *“I believe the Kenyan scientists still have independent thinking about GE science. Since 1996, we have not had a GE product.”* (PRp-PS4, Feb. 2008) While a NSS interviewee confirming the credibility noted:

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<sup>188</sup> Interviews with RSIIn-GP9, RSPu-PS7, PRp-PS4, RSAC-GP5, TAD-NSS6, TAR-NSS1, TAN-NSS4, TRTp-NSS3. ATp-PS3 and TAN-NSS2.

*“There are quite a number of people within NBC who are quite independent. They are not necessarily going by what the Americans want. Professor S [NBC chair] is very clear and open and when some of these things come up [attempts to influence], he will say the best thing is this way for this country [and would suggest]...we need to go that way, not this way.” (TAN-NSS4, technology advocacy, regional NGO, Oct. 2007)*

Further, scientists had learnt and acquired technical understanding of GE issues that enhanced science-based and independent reasoning as argued by the then chair of the NBC: *“NBC members are now more experienced on how to handle issues. I don't think any potential compromise would go far.” (ATp-PS3, Nov. 2007)*

This analysis still leaves some unanswered questions related to the balance between the credibility of scientists and the potential of exogenous pressures to influence scientific practice. These issues are revisited in the next chapter.

### **6.3.3.2 Credible national regulatory checks**

As much as interviewees admitted that there is likelihood of GE researchers being influenced by pro-biotechnology partners through the research projects, they argued that there were enough regulatory checks to thwart any attempt to influence the outcome of the regulatory process:<sup>189</sup>

*“Because other regulatory frameworks are in place and because our approvals are strictly based on scientific risk assessment, compromise will come out quite clearly. I do not think they [scientists sitting at NBC] can go far in influencing. The NBC is not made up of scientists alone. If you go there with your vested interests as a scientist, there are these other scientists from other organizations. As much you may want to influence, there are these others who represent different interest groups of Kenyans.” (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)*

Confirming the NBC credible approach to decision-making processes, one GE practitioner who has been an applicant perceived the NBC to be firm in its decisions:

*“Ideally the donor would have wanted us to [do things differently] but our regulator said no, [the vaccine trial] has to be confined. So I am very happy that we [NBC, research scientists & Kenyan regulators] managed to stand our*

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<sup>189</sup> Interviews with RSPu-GP7, ATp-PS3, PRp-PS4 and TRTp-NSS3.



*ground and still have the trial confined, although it didn't turn out the way they [research partners & donors] wanted."* (RSPu-GP7, animal research scientist, PRI, Jan. 2008)

Others felt that there were adequate safeguards to enhance a credible process driven by national interests rather than interests of specific groups.<sup>190</sup> One GP interviewee who has been in the sub-committee drafting the biosafety bill commented:

*"The influence [by pro-GMOs players] is not much because sub-committees are national teams who are government institutions, so international organisations are not influencing final content of policy documents. They expressed their concerns through various channels but the final national team made the decision. I would say if allowed, NGOs can drive the process. They have other agendas but national interests should be upheld."* (RSPu-GP1, research scientist, PRI, Jan. 2008)

Two interpretations can be drawn from this analysis. First, this analysis seems to contradict the earlier presented scenario that government coordination role of regulatory process was masked by integrated activism of scientists and pro-biotechnology actors. Second, the analysis seems to point towards the government firm control of the process, and therefore not a passive actor as portrayed in the earlier discussion. Both these scenarios have implications for the conclusion drawn in relation to potential influence of the regulatory process, instruments and outcome of regulatory decisions by scientists discussed further below (see section 6.3.3.4).

### **6.3.3.3 Resistance from anti-bill groups**

Critical analysis of media reports and accounts of interviewees suggest that the opponents of the bill consistently campaigned against the bill and hence had an influence on the process and public opinion. These efforts to discredit the bill, worked against interests of pro-GE proponents as one journalist explained:

*"I pity the GE proponents in Kenya; they are not quite articulate in pushing their agenda. Something very small sparked off by the opponents tends to have the ear of the population or to win the hearts of the majority. The proponents*

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<sup>190</sup> Interviews with RSIn-GP3 and RSPu-GP1.

*are usually overwhelmed by the opponents.”* (JO-NS7, journalist, local daily, Mar. 2008)

Fighting the bill by opponents was one activity that disappointed those who were pushing for its enactment as discussed in Chapter five, section 5.6.1. One scientist confirming this lamented:

*“But unfortunately they have an upper hand...they went to the streets which the president considered more than the technical arguments in parliament. But because of their methods which scientists cannot do; we are not going to carry placards; it captures the public eye and actually takes the day. They actually won, whether we want to believe it or not.”* (RSIn-GP2, research scientist, IRI, Dec. 2007)

Consequently, the government made various attempts to engage the opponents (NCST, 2007; RoK, 2008b). The BioAWARE initiative (RoK, 2008b) championed by the scientific community in the biotechnology and policy arena was linked to the controversies surrounding the biosafety bill and GMOs.

#### **6.3.3.4 Conclusion with respect to safeguards**

From the foregoing observations alone, it is difficult to conclude that the different safeguards curtailed potential influence of regulatory outcome particularly the biosafety bill in terms of content. This is because two parallel bills with opponents' preferred content tabled in parliament to counter the government biosafety bill were rejected.<sup>191</sup> Further, a number of scientist interviewees still felt that the bill was weak to withstand challenges during implementation (see section Chapter five, section 5.6.2). How then would the bill be found to be weak by the same scientists whose active role in the drafting was confirmed by many interviewees? Might this then confirm the government control of the process in a bid to balance its promotion of biotechnology for economic competitiveness agenda and its role in safeguarding citizens concerns with regards to

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<sup>191</sup> A bill tabled in parliament by Mr. Nakitare, a member in the 9<sup>th</sup> Parliament. In the 10<sup>th</sup> parliament, he was not re-elected. However another bill “the biotechnology and biosafety bill, 2008” was tabled in 2008. It was rejected and consequently overtaken by events when the biosafety bill was approved in Dec. 2008 and consequently enacted into Law the following year.

biosafety? These issues warrant further exploration and form a substantive part of the next two chapters.

The inconclusive nature of this discussion leads to a question related to how influence should be assessed, perhaps pointing towards the most important aspect of influence - implications for scientific practice. The next section explores visually how thoughts of scientists (perceptions) translate into influence (practice), paving way for exploration of policy recommendations for improved scientific practice in the subsequent chapters.

## **6.4 Relationship between perceptions of regulations and regulatory practice**

A cognitive mapping technique was used as an analytical tool to organize the interviewees accounts related to perceptions of regulations, the regulatory process and consequently linking them to the regulatory practice (see Chapter four, section 4.7.3). The constructed visual maps explain this interrelationship. Summary of similarities and differences within and across the three groups of scientists based on perceptions and related regulatory action were organised and presented in four different maps. Three are individual group maps (PS, NSS and GP interviewees) while the fourth map brings together the views of all the scientists based on the commonalities identified amongst the three categories of scientists. Visual maps are important in linking the thoughts or perceptions to actions (see more details including how maps were constructed in methodology chapter, section 4.7.3).

### ***6.4.1 Reading the cognitive map***

The short phrases used in the maps refer to ideas or concepts while the arrow links (>) running upwards, from down towards higher level, are read as “may lead to” and represents intended goal or outcome. The tail of the arrow is representative of a

triggering event or drivers. The ellipsis (...) where it appears should be read as “rather than” while an arrow with a negative pole (–) denotes ‘leads to a negative action’.

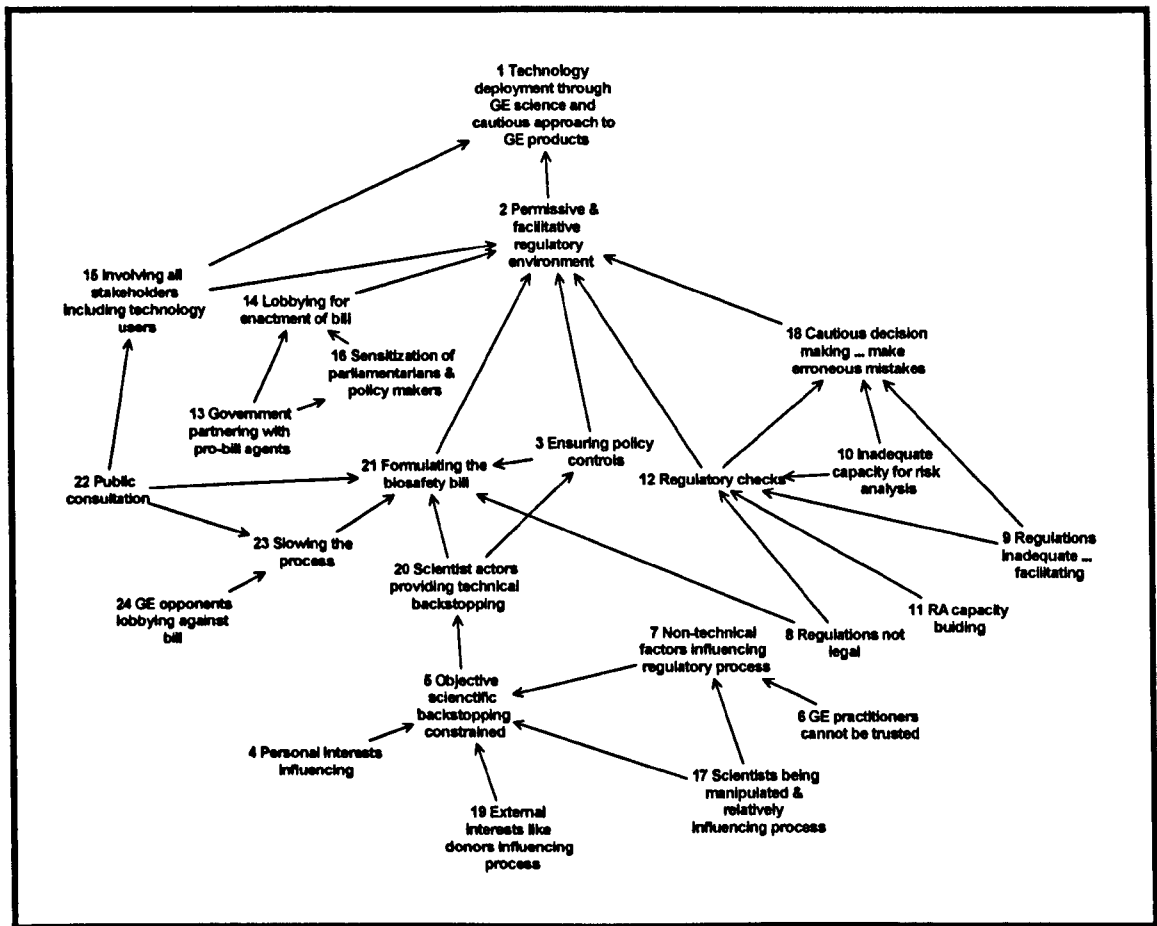
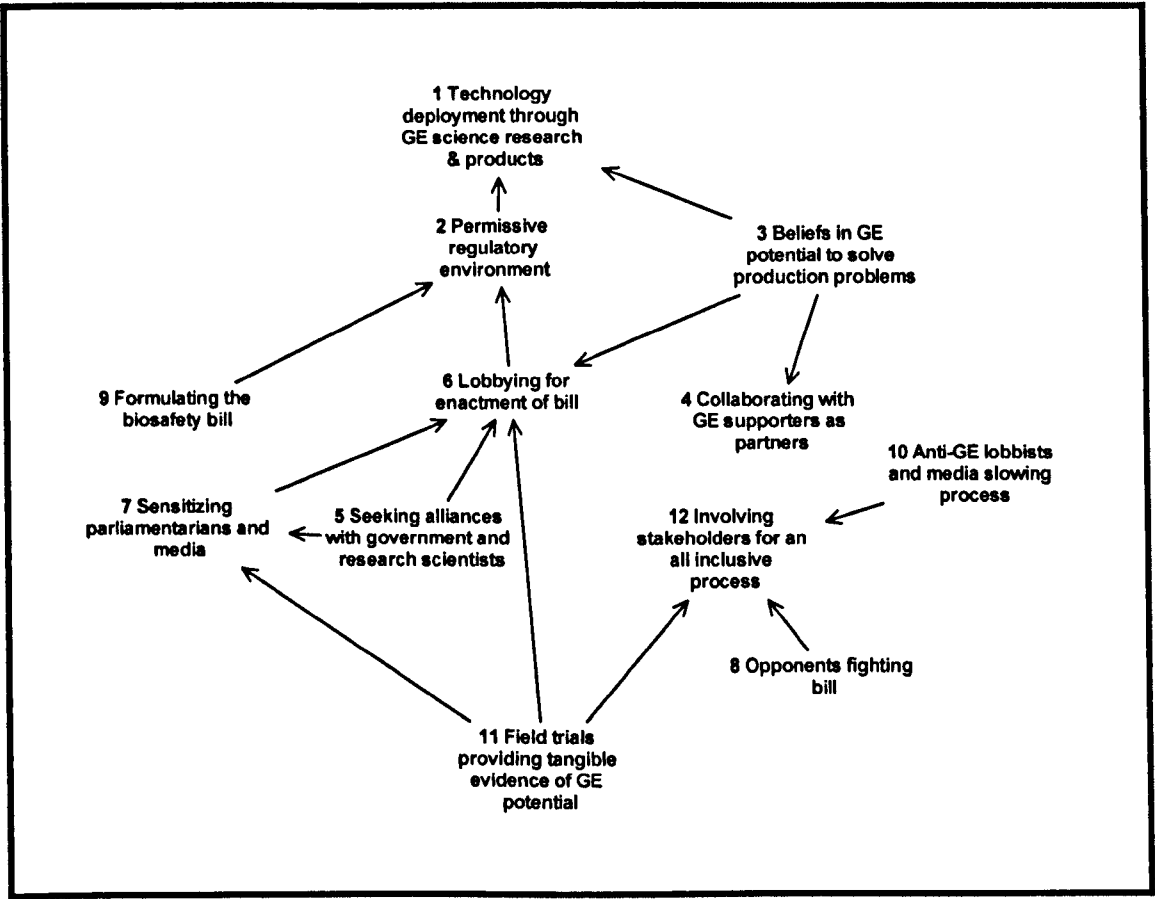


Figure 3: Map of Policy Scientist interviewees (PS)

These scientists are working with frameworks that are both process based and product based (concept 1). They are interested in an effective and facilitative regulatory framework that would enhance implementation (concept 2). They have views on both policy process and regulatory decision-making process (left hand side and right hand side of the map respectively). They also have views on the weaknesses of the decision-making process (concepts 9, 11, 8) but are able to undertake actions to address these weaknesses (concepts 11, 12, 18). Regarding policy process, they perceive the biosafety bill as a gateway to a permissive and facilitative regulatory regime (concept 2) so are partnering with GE scientists and others to; provide technical backstopping

(concepts 20, 21), educate (concept 16) and lobby (concepts 14, 13). However they were conscious of perceived endogenous and exogenous pressures influencing objective science-based regulatory process (concepts 6, 17, 19) hence initiated controls (concepts 3, 22, 15). Opponents of the bill are perceived to be slowing the policy process (concept 24 & 23) hence enticed to become stakeholders in the process (concepts 22, 15).



**Figure 4:** Map of Non State Scientist interviewees (NSS)

These scientists are working with frameworks that are both process and product based (concept 1). They are interested in a permissive regulatory regime (concept 2). They believe in GE technology and its potential to address agricultural production problems (concept 3) through deployment of biotechnology products (concept 1). They therefore support the deployment & regulatory process through enlisting of relationships

(concepts 4, 5, 7, 12) to establish a permissive regulatory environment (concept 2) through the bill (concepts 9, 11, 6) and counter the opponents (concepts 8, 10).

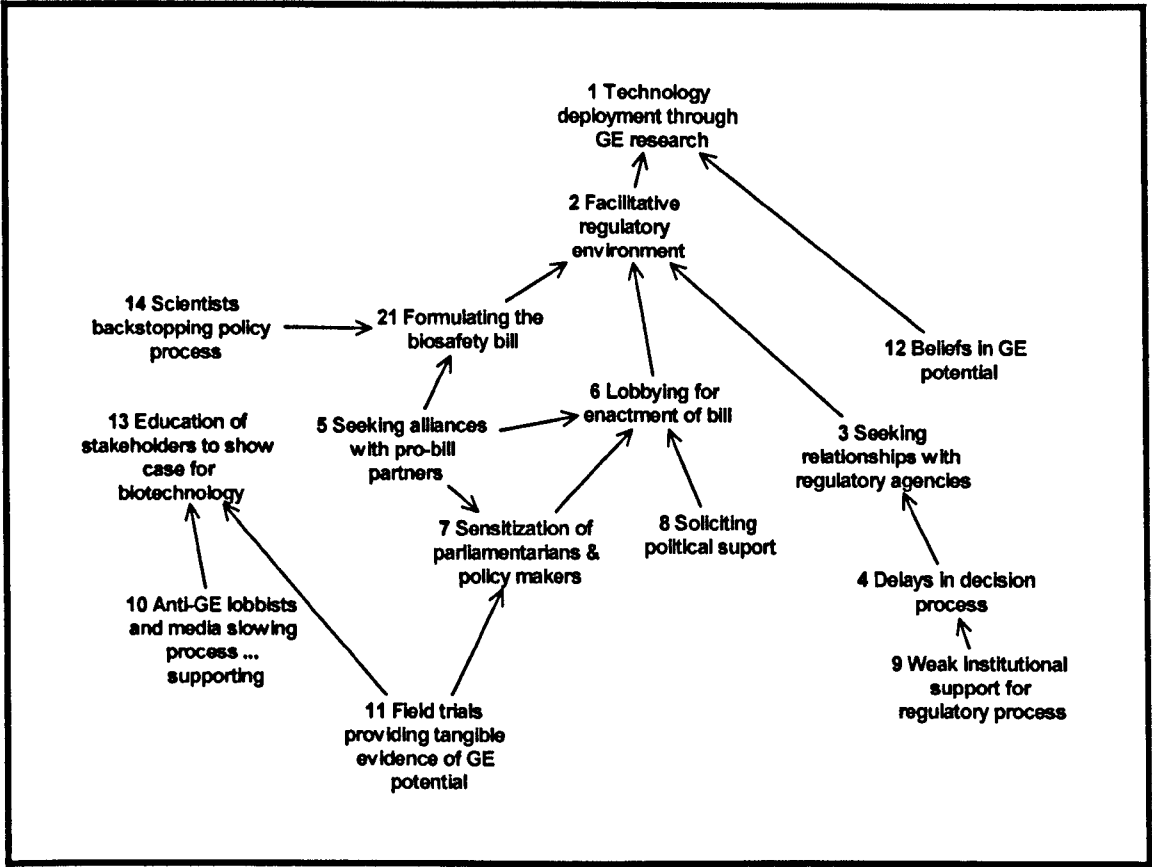


Figure 5: Map of GE Practitioner interviewees (GP)

As practitioners, these scientists may be perceived to be pro-GE technology and process based (concept 1). They are working with regulatory frameworks that they perceive to be constraining their work. They are keen on a facilitative regulatory environment (concept 2) that they perceive would enhance technology transfer (they believe biotechnology has a potential-concept 12) and believe biosafety bill is the gateway to achieving this goal-technology deployment (concept 1). The decision-making process related to this science is of interest to them (concepts 4, 9). So, they are actively involved in the regulatory policy process through technical backstopping (concepts 14, 21), lobbying (concept 6), enlisting relationships (concepts 3, 5, 8) and educating/awareness creation (concepts 7, 11, 13). They also perceive opponents (media

& GE activists) to have been working against achieving a facilitative regulatory environment (concept 10) so have actively engaged media in education (concept 13) in an effort to enhance positive reporting about GE science.

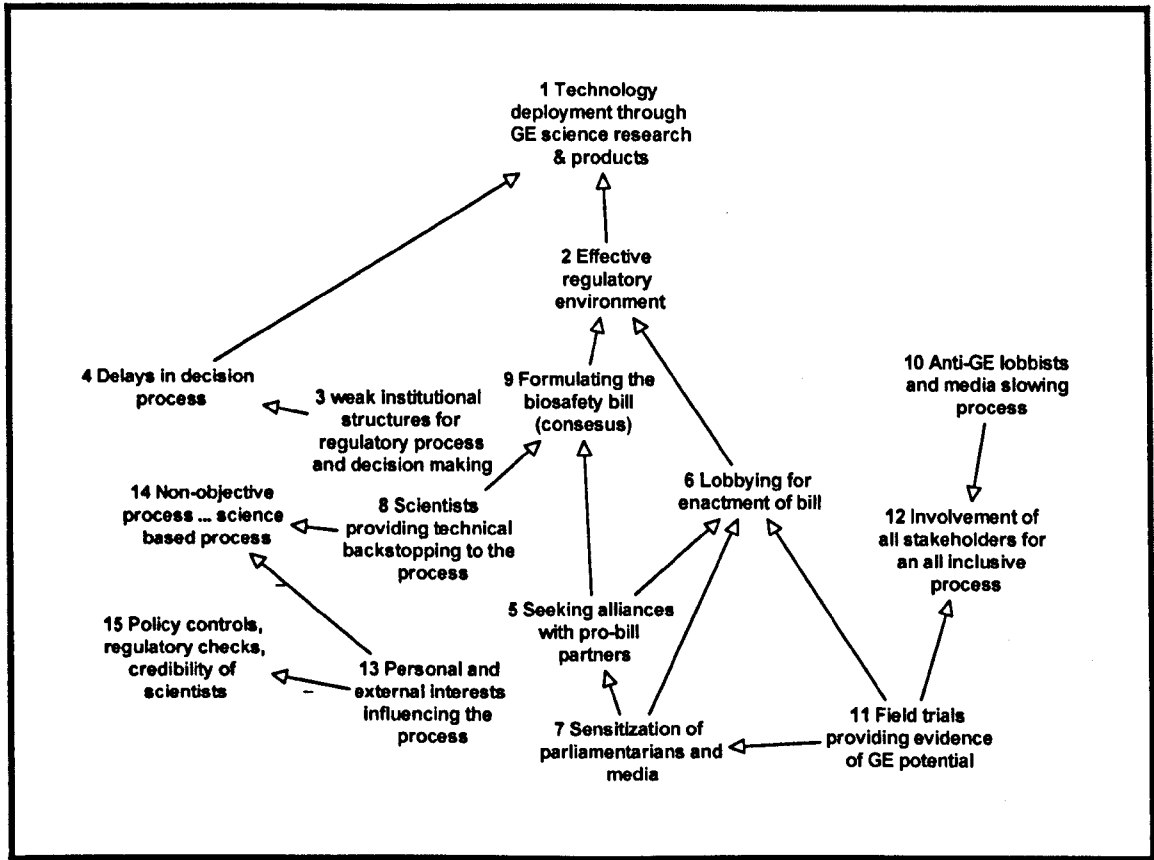


Figure 6: Scientists shared map

This map shows the commonalities in terms of views and actions. The scientists agree on a relatively effective regulatory process (concept 2) and are in agreement that biosafety bill would lead to this (concept 9). Partnerships are enlisted towards enactment of the bill (concepts 5, 6, 8, 7) and addressing institutional weaknesses (concepts 3 & 4), while field trials are used as tangible evidence in sensitization of policy makers (concept 11). The opponents are perceived to be acting against the process (concept 10) and therefore inevitably brought to the process as stakeholders (12). Interests that may influence the process negatively (concepts 13, 14) are checked through controls (concept 15).

#### ***6.4.2 Conclusion with respect to visual illustration of relationship between perceptions and practice***

This graphic representation of views related to regulatory process and instruments suggest a strong interrelationship between the perceptions held by the Kenyan scientific community about both biotechnology science and the desired regulatory regime. Consequently, critical review of the maps points towards a proactive and engaged nature of both the scientist actors and the regulatory process. The maps complement the data analysis and interpretation that has informed the empirical chapters and policy recommendations in Chapter eight. The maps do not however reveal the underlying factors that underpin this practice, and nature of learning and knowledge produced through the prominent relationships around the different activities and processes. These factors are substantively covered in other sections of the empirical chapters.

#### **6.5 Chapter conclusion and summary**

The argument advanced in this thesis relate to how scientists impact regulatory process and instruments through the processes of learning and knowledge production activities they engage in. Shaping of the regulatory process and instruments is important in understanding the role of incremental learning and knowledge production dynamics in scientific practice. Evidence in this chapter suggest that for the scientists to achieve their desired regulatory goal, cooperation is key and knowledge produced individually must be augmented by other forms of knowledge to impact policy change. What is however crucial to note is the nature of influence that is ultimately directed through this interest driven proactive policy process as graphically presented through the visual maps.

The focus of this thesis is the scientific community, and their role and behaviour related to implementation of regulations. The exogenous and endogenous pressures and motivations that confront scientists as they implement regulations cannot be taken for granted as they are points of reference in terms of the potential to impact behavioural



change. In addition, the tensions that this process generated relating to regulations non-compliance, science communication and controversies around the biosafety bill cannot be ignored as they have implications for implementation of policy instruments and broader innovation process. Table (10) below summarises these practice based issues and the related findings that form the basis for exploration and discussion in the next chapter.

**Table 10: Summary of research findings on role of scientists in regulatory process & instruments**

CHAPTER SUMMARY	
Issues	Findings
Involvement of scientists in GE work & regulatory process spurred by diverse motivations & opportunities.	These motivations and opportunities are linked to diverse interests and values.
Tensions emanate during trials execution related to regulations non compliance.	These are caused by varying perceptions of regulations & attitude related factors.
Communicating GE science	Poor public communication and biased reporting impacted by many non technical factors like fear of misinterpretation and interests.
Role of scientists in regulatory process & instruments	<ul style="list-style-type: none"> <li>-The different activities were shaped by the four different regulatory phases. Role in the early phase received no contestation but role in latter phases were characterised by controversies and activism.</li> <li>-Activities advanced within and around different relationships were rhetorical and persuasive in nature towards influencing the biosafety bill. These relationships were spurred by resources and varying interests.</li> <li>-Overall, scientists and their affiliated knowledge nodes have been sources of different types of knowledge that has relatively impacted policy and regulatory process.</li> <li>-The influence of regulatory output is contested supported by claims of policy safeguards raising questions about governance and control, and how influence should be analysed.</li> </ul>

These key findings relating to scientific practice present the scientific community playing out different roles in different cultural realms, and perhaps unconsciously or consciously, learning occurs through interactions, while knowledge is disseminated in different ways. There is a complex interplay between scientific behaviour and the associated roles, and the underpinning factors that seemingly direct practice and outcome. This evidence-based complex scenario deserves a critical analysis to establish the theoretical and policy ramifications which is the subject of the next chapter.

### 7 Discussion

#### 7.1 Introduction

Biotechnology innovation is advancing in a relatively unprecedented pace that challenges the evolution of the requisite structural, institutional, cultural and social processes that are pertinent for a coordinated social and policy change (Tait *et al.*, 2006). Pertinent to this thesis are the institutional and cultural changes embodied in the evolving biotechnology innovation system that illustrate features of Mode 2 knowledge production terrain described by Gibbons and Nowotny and their colleagues. Biosafety regulation, being one of the requisite institutional changes for management of biotechnology knowledge is however bound up in the broader innovation system transition. In this chapter, the cultural and institutional shifts impacted by the biotechnology revolution in the context of scientific practice and regulatory practice, and the implications for the emerging regulatory instruments are analysed.

The chapter is organised as follows: Firstly the perceptions of regulations and practice are placed within the overall knowledge theme in which this thesis is grounded. Secondly, specific issues that emerged in Chapters five and six are discussed in order to develop an understanding of the perceptions of scientists on regulations and regulatory practice, and their role in biosafety policy processes. This is followed by an analysis of role and behaviour of scientists in the regulatory process including related tensions, in the context of the evolving knowledge production terrain. The discussion ends with a review of the role of the scientific community in the regulatory practice relative to the influence of regulatory instruments.

## 7.2 Institutionalisation versus adaptation

Developments in the Kenyan modern biotechnology in agricultural innovations as discussed in Chapter two have impacted major institutional changes at the technological and policy level. It is also important to note that knowledge drives the purportedly scientific and technical decision-making processes and is indeed a key resource shaping the overall institutionalisation process.

The transdisciplinary nature of biotechnology innovation and related governance has called for integration. This integration was however perceived by many interviewees to have an economic connotation due to interests of the different knowledge intermediaries. Moreover, the political economy of Kenyan biotechnology as externally funded creates suspicion and distrust among players. Some interviewees felt this may promote bias especially in dissemination of information from GE trials which would purportedly promote interests of funding institutions, particularly on social matters related to risk of biotechnology products. The distrust and suspicion views were shared independently by various groups of interviewees irrespective of whether they are practitioners, public or in policy arenas.

These issues are not new in the GMOs debate and reflect complex political, social and economic challenges that characterise governance of modern biotechnology. As extensively debated by proponents of governance theory (cf Tait and Lyall, 2005; Lyall *et al.*, 2009a), they invariably expose the difficult terrain that characterise institutionalisation of the new life sciences where diverse interests and values inevitably drive the policy processes.

From the perspective of theories of knowledge, the involved dynamic institutionalisation and adaptation by social actors portrays a redistribution of knowledge from the innovation communities who comprise the research fraternity (who

previously were perceived to be experts in their own right) and the technology suppliers, to policy makers and public. It mimics the integrated mode of knowledge generation and flow characterised by changing knowledge relations and the emergence of new networks of knowledge users and producers (Gibbons *et al.*, 1994; Nowotny *et al.*, 2001; Haas, 2004; Philips, 2007). This notwithstanding, these theories do not explain vividly the behavioural changes that players experience simultaneously alongside the linked institutional changes which are not confined to research arena as implied by proponents of Mode 2. Interestingly, the players involved may even be unconscious of the implications considering the shifting of perceptions by actors prompted partly by the dynamic relationships and cumulative learning. This impacts the ensuing knowledge use as discussed in the subsequent sections.

### **7.3 Perceptions of regulations and regulatory practice**

Chapter five highlighted key issues which suggest that perceptions of interviewees changed over time which can be linked to the four significant regulatory phases discussed in Chapter two. The institutional dynamics involved have significantly shaped the views of the interviewees about regulations and practice. This section is grounded in this changing institutional context in an attempt to address the first research question: *the perspectives of scientists on implementation of biosafety regulations and reasons behind the expressed views.*

As demonstrated empirically in Chapter two, the development of a regulatory system has been bounded up in the broader biotechnology innovation process. This distinction makes it possible to relate the perceptions related to regulatory process to the broader innovation process and scientific practice. This is because the twin processes of biotechnology innovation and regulatory process are highly interlinked and iterative as Fig 1 in Chapter one, section 1.1.3 illustrates.

### **7.3.1 Contested risk assessment and decision-making processes**

#### **7.3.1.1 Challenges in decision-making process**

The National Biosafety Committee (NBC) has been the interim institutional structure (as a boundary organisation) through which regulations and decision-making processes have been implemented. The interim structure has indeed facilitated biotechnology deployment and establishment of a biosafety regulatory regime. However, this thesis has brought to the fore certain inefficiencies inherent in this interim structure related to institutional weaknesses and coordination of a transparent biosafety bill formulation.

The strength of any regulatory system would be determined based on legally binding and clear regulatory standards (Maclean *et al.*, 2002; Jaffe, 2006). Without undermining the regulatory purpose that policy targets expected the regulations to articulate, without clear regulations (at least prior to the Biosafety Act, 2009), the Kenyan regulatory process was left to different interpretations and practices. It was therefore not a surprise that many interviewees perceived the process to be inefficient.

Effective implementation of biosafety regulation is determined to a large extent by institutional and capacity issues (Maclean *et al.*, 2002; Traynor *et al.*, 2002). Lack of clarity of regulations brought about different conflicting approaches to risk assessment and consequent decision-making processes. This challenged the scientific and technical process advanced by the main regulatory instruments and desired by many interviewees. This notwithstanding, the big question that is posed here relates to how the challenges reported by interviewees impacted regulatory practice and with what implications for scientific practice (this is discussed further on in the chapter).

#### **7.3.1.2 Science based process versus value laden process**

It is widely accepted that risk assessment procedures and consequent decision making in regulation of GE activities should be based on sound science. However, accounts of

scientists seem to put to doubt the objectivity of the decision-making process which many interviewees repeatedly described as science-based or scientific. The regulatory instruments that have since guided risk assessment also emphasise on science-based process (RoK, 1998; RoK, 2009). The challenges and objectivity issues discussed here relate to conflicts and tensions encountered in science policy debates (Newell, 2002). In science-policy related activities that include use of scientific expertise, objectivity as seen from a sound science perspective and transparency are highly constrained (Levidow and Carr, 2007). The tensions that characterise the risk assessment (RA) and decision making styles adopted by the NBC put the issue of “objective” decision-making process into contestation in a manner similar to the case of European Food Safety Authority (EFSA) illustrated by Levidow and Carr (2007). The deliberations of EFSA, just like the NBC, are “officially” transparent and objective. However conflicts and tensions have arisen due to difficulties experienced in an attempt to separate science and policy since the two overlap significantly (*Ibid.*; 888).

### **7.3.1.3 Scientific versus social interpretations in decision-making processes**

Contrasting arguments run through narratives of interviewees related to perceptions of two related subjects: one, role of science in decision-making process and two, representation and engagement in biosafety bill formulation. The “scientific” interpretation of regulatory process emanates from the “objective science” approach to regulations. In contrast, “social” interpretation seems to favour a broader view that encourages integration of wider supposedly non-science considerations. These interpretations, spread out across different groups of interviewees (scientists and non scientists) reflecting diverse framings of GE technology and regulation resonate with Hajer’s (1995) conception of GMOs discourses. The scientific arguments emanating from some pro-biotechnology coalition members reflect the “sound science”, “science based”, “objective” and similar terms that protagonists use in their debates about GE

science. On the other hand the frames like “subjective” and “biased” characterised the positions or beliefs of those who hold a different perspective (mainly opponents).

The articulation of these arguments may be construed to mean that scientists may still be trapped in their disciplinary based scientific thinking (Mode 1) where science was perceived to be a neutral judge for the solution to policy problems. NBC was a perfect sphere for deliberation of the social and scientific confrontations inherent in GE debate where science-policy politics challenged the dominant and purportedly normal scientific practice.

#### **i. Understanding the social and scientific interpretations**

Kenyan scientists interviewed in this study expressed desire to have the social and science issues separate in biosafety regulation to enhance technology transfer and regulations implementation. However, there was a clear distinction in the way the interviewees interpreted the two concepts. When it means moving the science forward (to products) the social must be given space as illustrated by the following remark from a senior policy scientist:

*“At the end of the day it depends on what you want as a country. Do you want to sit back and hold on the science until you get the perfect [legal regulatory environment] situation because these are trials? Science does not change, law or no law; science remains fixed because it is something that is justified. GE is a science and existing regulations are science based. Biotechnology is a process that leads to a product. There are no laws to protect the product of science, then there is a problem because the products are going to be consumed and that is a decision you cannot make with science alone.” (PRp-PS4, regulator & policy advisor, regulatory agency, Feb. 2008)*

Boundary work offers insights that can be drawn to interpret the contradictory perceptions oscillating between social and science arguments. As Gieryn (1995:440) contends, boundary work tends to separate science from non-science. This separation conceptualises science and politics as two different social activities. In practice, this

separation is problematic as exposed by the current study. Through the scientific community engaging in boundary work, two objectives could be met. Firstly as experts, they struggled between science and politics in an endeavour to uphold the cognitive authority of science among scientists and outside this group (Gieryn, 1995:434-435). Secondly, as policy makers, they used scientific knowledge to legitimise the regulations (or regulatory process) to enhance objectivity and in the process re-configured the scientific facts to balance the science and social concerns (Jasanoff, 2004b). One clear reason for separating social from scientific in the Kenyan context was to legitimate the regulatory process which proved to be problematic, at least for the innovation communities like scientists.

Knorr-Cetina (1995:146) describes the origin of these artificial separations by noting that “traditionally, social has been seen as external to the conduct of science.” Jasanoff (2004a:2) also debates the conflicts between these arguments using the “co-production” framework<sup>192</sup> and argues that scientists tend not to see the bigger picture, that any form of knowledge is a product of social work. Perhaps what they fail to realise as affirmed by Jasanoff and Knorr-Cetina is that, knowledge production involves “negotiation” and “translation” of results that highlights the social character of that process. During knowledge production scientists grapple with issues which they label as scientific and non-scientific (Knorr-Cetina, 1995:154). Consequently the context and content of scientific activities are continuously reconfigured and tacit agreements about what is science and non science are negotiated to address controversies (Callon, 1995:50-63).

## **ii. NBC as a boundary organisation**

The NBC (as a government instrument overseeing boundary work) seems to have played a big role in shaping views of scientists. Boundary organisations endeavour to

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<sup>192</sup> Co-production implies that “in broad areas of both present and past human activity, we gain explanatory power by thinking of natural and social orders being produced together” (Jasanoff, 2004a:2).



draw an artificial line between scientific and political processes in terms of authority and action through negotiation (Jasanoff, 1990; Guston, 2001). The work of NBC seems to have concretized or reinforced the social and scientific arguments in practice. Firstly, NBC derives its understanding of GE technology and biosafety from work of scientists. This way, what scientists provide (e.g. for RA) may be construed to be scientific if it is finally accepted for decision making by the NBC. If it is rejected, then it may be categorised to be non-scientific (or social).<sup>193</sup> Second, its practice relating to how it conducts its business pertaining to regulation of GE technology confuses observers. It is confusing and contradictory how the process can be based on sound science yet decisions made are consensual.

Although the intention of the NBC is to bring harmony between science and politics, the institutional weaknesses exposed frustrated scientists as it endeavoured to separate social from science.<sup>194</sup> For instance Mugo *et al.* (2005:1492), reacting to the constraining and confusing nature of regulations, noted: “there have been cases of conditions becoming stricter and non science based decisions influencing the process.”

#### **7.3.1.4 Conclusion with respect to contested processes**

The issues reported here are not new but reinforce the controversies in governance of environmental and the new life sciences (Miller, 2004; Lyall and Tait, 2005). However, use of the concept of boundary organisation in analysing the effectiveness of institutionalised structures and actors’ practices (cf Kristjanson, 2008) enriches the governance theories.

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<sup>193</sup> This has implications for public policy in that the NBC selectively decides who, what and which evidence to consider scientific for decision making purposes, making it possible to exclude particular views or sources in the process. This can affect trust (scientists not trusting NBC and activists not trusting the scientists and government).

<sup>194</sup> It may be concluded that this governance style adopted by NBC is confusing to actors and has implications for perceptions because scientists tend to construct their images regarding what is social and scientific based on this.

### ***7.3.2 Prospects and risk perceptions in framing regulation and regulatory processes***

#### **7.3.2.1 Technological prospects**

One main argument expressed by all the scientist interviewees (except one from civil society) is that biotechnology innovation can only achieve its potential to address production constraints if supported by an effective regulatory regime. This being the case, the sentiments about the nature of biosafety regulations and the institutional structures to support implementation were based on this view.

These findings are not different from what others have reported regarding the history of biotechnology research in Kenya. They point out the direct correlation between agricultural biotechnology research and its governance (Ayele. *et al.*, 2006; Harsh, 2005; Harsh, 2008; Mugo *et al.*, 2005; Odame *et al.*, 2002, 2003). GE technology was the trigger for the existing regulatory regime. Odame *et al.* (2002, 2003) for instance highlights how the Kenyan regulations were driven by technological pressure. It is therefore not surprising that interpretation of regulations would relate to the historical background. Thus, any held perception is likely to be interpreted in terms of whether this technological pressure has been sustained, curtailed or enhanced.

Many scientists seemed to have formed an idealised stance about the direct and seemingly uncontested prospect for GE technology to deliver solutions to agricultural problems. According to Scoones (2002), it is not uncommon for scientists to take an idealised stance regarding GE technology as a “magic bullet.” This stance nevertheless masks the broader social issues associated with biotechnology innovation as some scholars have observed (Hisano, 2005; Scoones, 2002; Andanda, 2006). This stance is concretised at the regional and international level. For instance, a FAO report of 2004 seems to support that GE technology may be explored and should be given a chance in addressing food security challenges. Other regional policy initiatives also seem to

support the same view (Juma and Serageldin, 2007). “Biotechnological determinism” has been used to describe this technological mindset referring to a linear thinking that assumes that production of knowledge leads to production of economic production (Levidow, 2007; Jasanoff, 2002). It assumes that a technology “moves down a pre-set path” (Harsh, 2008:48) and ultimately achieving global competitiveness (Levidow, 2007). This seemingly narrow thinking underplays the complex institutional issues inherent in innovation systems that call for holistic thinking (Hall, 2005; Clark, *et al.*, 2003).

#### **7.3.2.2 Risk based regulatory approach**

Many interviewees were sceptical about GE technology and its safety. The regulatory instruments in addition to the risk management measures imposed on the trials were actually regulating potential risk to the environment. But different interpretations of risk exposed the preferred regulatory approaches and decision-making processes.

Policy scientists, driven by fear linked to public accountability and stability of their institutional careers preferred cautious but permissive regulations. Caution was to safeguard against any unexpected risk that may be posed by the GE trials and facilitation was to enhance research under confinement thus minimising chances of gene escape (KEPHIS, 2004a). Balancing the two was achieved through drafting of regulations that could only facilitate GE trials under confinement (RoK, 1998). This early cautious approach to regulations reaffirms what other scholars have reported. Sander (2007) for instance asserts that Kenya initially adopted a precautionary approach to biosafety regulation due to lack of capacity and knowledge to institutionalise biosafety and secure safety in modern biotechnology. Paarlberg (2001) concluded that, Kenya’s regulations were “precautionary” and restricted the entry of GM research material. The current study reinforces these claims by identifying uncertainty and fear

of the unknown associated with biotechnology as a contributing factor to the precautionary position adopted.

In case of other countries' risk regulation approaches (cf EU precautionary approach), caution would be aimed at addressing social conflicts related to risk uncertainty (Levidow *et al.*, 1999). The uncertainty revealed in the Kenyan case was not directly related to public safety, but rather uncertainty sparked by constrained freedom of regulators from making independent regulatory decisions. This was linked to lack of legal instruments that would guide RA and protect regulators irrespective of regulatory decisions made. The following comment that has also been used in Chapter five, section 5.5.2.1 supports this analysis:

*"The problem with regulations and the regulatory system in Africa which is still developing, the individual person as the regulator has a problem because you fear that if I allow this thing and something goes wrong, you will be the one to be slaughtered. So the fear that you might get cheated and you do the wrong thing and you lose your job and your children go hungry." (RSIn-GP2, research scientist, IRI, Dec. 2007)*

This approach to regulation although risk based mimics the government's approach (Tait *et al.*, 2006) and the EU precautionary style which advances "it is better to be safe than sorry" (Marchant, 2001:143). Indeed many interviewees consistently likened the Kenyan regulatory decision-making process to Europe's precautionary regulation, expressing their dissatisfaction with restrictive regulations that seemed to constrain GE technology advancement beyond confinement.

The Kenyan style of regulatory decision-making process is not unexpected. From global, regional and local context, regulation of GE technology has adopted a risk approach (Cartagena Protocol, 2000; African Model Law; RoK, 1998, 2009; Andanda, 2006). But how these transnational and national contexts may have influenced the views expressed by the scientists may not be apparent. This notwithstanding, the data suggest

that the debates around product based and process based regulation (Tait and Levidow, 1992; Chataway, 1992; Jasanoff, 1995; Dunlop, 2000) had a major impact on interviewees' perceptions of regulations. For instance, the pro-biotechnology interviewees aligned themselves with product-based approach and tended to prefer risk judgement based on quantifiable risk and sound science. Some policy scientists and non scientists from civil society were however proactive and cautious and preferred "government approach" with some form of regulatory control. This implies that risk is value-laden, making biosafety regulation to be contested based on different interpretations of risk.

### ***7.3.3 Shifting perceptions of regulations and implementation***

Framing of GE technology as a key agenda in the agricultural revolution has increased the number of stakeholders in biotechnology innovation. At the early stages of the regulatory process in Kenya, there were no major concerns in the way biotechnology innovation was being governed. This may be associated with the purportedly few actors and the limited knowledge in the supposedly new science and related biosafety. During the technological and institutional transition from regulatory phase 1 to 4, the number of actors proliferated, with the civil society becoming a central player in the governance agenda in the latter regulatory phases. This increased the controversies with the framing of regulations shifting from promises (benefits) approach advanced earlier towards cautious (biosafety) approach. Framing of regulations in the context of prospects and risk brought to the fore the economic and political context driving the construction of views around regulatory process, exposing diverse values held by the scientific community and other stakeholders.

It is possible for perceptions of actors to evolve and change with time alongside the evolution of regulatory phases and technology development. Different reasons may be

attributed to this. Firstly, using innovation systems thinking, perceptions of actors in a dynamic system are not expected to remain static because of incremental learning that takes place as actors interact in different ways. Consequently as actors become familiar with both the technological and regulatory system, perceptions may also change based on the way they are governed and how regulatory instruments impact upon the intended outcome (Tait *et al.*, 2006). It emerged that the regulatory instruments were curtailing knowledge generation and flow more generally. Some of the experiences revealed by both practitioners and policy scientists indicate that certain aspects of the decision-making process were very frustrating due to undefined or lack of clarity of existing regulatory standards. The associated weaknesses seemed to emerge as the regulatory regime matured from regulatory phase 1 towards phase 4 as actors experienced regulatory constraints.

Further, scientists' regulatory preferences varied as the GE products moved from containment, field trials and the anticipated commercialisation. This change in perception along the product development continuum mimics the observation by Chataway *et al.* (2006) involving policy makers and industry managers in the USA and Europe. Based on different perceptions, these scholars could categorise different policy instruments as enabling or constraining.

#### **7.4 Role and behaviour of scientists in the regulatory process**

In this section, reasons behind the actions taken by the scientific community as they engaged in regulations formulation and regulatory practice are discussed in order to address the following research question: *how scientists shaped the evolution of the regulatory process and instruments*. The focus relates in particular to how risk assessment information was managed, how regulatory decisions were made, how field trials were managed, how information emanating from the field trials was handled, and

finally how scientists engaged in the development of regulatory instruments, particularly the biosafety bill.

#### ***7.4.1 Theoretical insights***

To enhance the analysis, insights are drawn from theories of knowledge (e.g. Mode 1 and Mode 2 thinking), innovation systems (IS), policy coalitions and science policy literature. The latter two concepts as described and applied by a number of researchers augment the application of knowledge principles through the understanding of the role of linkages in learning and knowledge dispersion. Policy coalitions, just like policy networks explain how knowledge and diffusion are applied in policy processes through influence achieved via interactions and negotiation (Lyall, 2007a; Sabatier, 2007). It enriches the understanding of relationships building and interactions advanced in the IS framework in which this thesis is grounded. Science policy and policy coalitions concepts further add value to the analysis by grounding Mode 1 and 2 practice in the political context under which biosafety regulation takes place.

#### ***7.4.2 Motivations for scientists and drivers of change in behavioural practice***

Scientists' motivations for engaging in GE technology and related regulatory activities coalesced around endogenous and exogenous motivations. The former reflect values and interests that are personal, social and sometimes technical in nature (e.g. publishing and fame). The latter is linked to contextual factors that confront the scientific community (e.g. external funding for purportedly public research). These different motivations albeit evoking the risk of conflict of interest, interplayed significantly to influence the views and behaviour of scientists. Consequently, shifting social identities, clear science policy roles and new forms of policy relationships were exposed.

### ***7.4.3 Scientists as experts in the regulatory process***

Scientists in their capacity as experts played two key roles in implementation of regulations, one as proactive agenda setters in matters of purportedly technical biotechnology subject and two, as resources for actors in practice, government and industry in the technical and non technical matters of biosafety policy. In articulating these roles, they provided expertise as individuals or corporately within institutional knowledge-based nodes (NGOs, government departments, research and academic institutions, and professional and disciplinary groups). Provision of scientific expertise is a role that all scientists are expected to be playing in uncertainty bound and complex technical problems (Haas, 2004; Weingart, 1999; Jasanoff, 1990). Indeed, the importance of scientific expertise in biotechnology regulation and environmental policies has not been disputed (Scoones, 2002; Keeley and Scoones, 1999). However, different challenges arise related to the way experts play out this role and which is inadequately addressed by knowledge dynamics literature.

Gieryn (1995:440) and Haas (2004:572) point out that social and cultural factors may constrain production of knowledge. For instance the different intermediary groups that the scientific community belong to constrain independent thinking and policy actions. This may imply that the knowledge generated from such knowledge nodes may be subjective and has implications in its potential to misinform or manipulate science policy processes. In the Kenyan context, experts seem to be coming from a few institutions namely research institutions, regulatory agencies and academic institutions, but who are connected to a wider stakeholder or intermediary groups outside the government circles. This may not be surprising because capacity in both biotechnology and biosafety is being developed and therefore experts serve multiple roles as GE technology experts, biosafety experts, risk assessment reviewers and policy advisors.



Most of the interviewees have served in multiple capacities in the science policy arena at different times in their careers.

Multitasking demonstrated in Kenya with respect to expertise is common in the science policy domain as Jasanoff (1990) and Rothstein *et al.* (1999) contend, referring to regulatory systems in the USA and UK respectively. However, there seems to be a problem in the way Kenya's expertise role is played out. It reflects an incomplete model of expertise demanded by a socially desirable knowledge production atmosphere (Nowotny, 2003). A complete model of expertise (that would produce knowledge that meets the demand of an increasingly informed public) should be broader perhaps coming from civil society who may be representing public or non-scientists. Nowotny contends further that democratising expertise is problematic and tensions tend to emerge. Perhaps what the scientific community (particularly the policy makers) seems not to be aware of is the difference between scientific or technical expertise and the broader expertise. This area needs to be addressed through appropriate institutional policy and practice reforms (see Chapter 8).

#### ***7.4.4 Scientists behaviour reflecting shifting identities***

Scientists had various obligations that they kept in mind as they endeavoured to implement the regulations. They talked of meeting their basic personal scientific goals as researchers in their various rights, meeting their organisational obligations as employees, demonstrating the usefulness of GE especially through field trials, attracting financial support for individual projects or organisations and responding to policy demands. Consequently, several types of strategies were initiated and different relationships forged to achieve these obligations and motivations.

#### 7.4.4.1 Diverse relationships during implementation of regulations

**Researcher-patron relationship:** The research terrain has changed with reduced government support for research (most interviewees expressed displeasure with the government regarding this) and this has made researchers seek resources elsewhere. Some of these external sources of funds have been the biotechnology industry and donor organisations. Consequently scientists have signed research contracts with the biotechnology proponents within the increased Public Private Partnerships (PPPs) (see also Ayele *et al.*, 2006). Supposedly, easily available research funds became a motivation for engaging in GE research as one interviewee argued:

*"I found that most scientists hijacked the train from being conventional breeders to biotechnology for one very unfortunate reason; the money. They jumped from their normal research and it is like everybody wanted to be in the biotechnology industry, there was money. As a scientist in your laboratory somewhere you may be sitting there asking for reagents for the last 2 months and then biotechnology comes with money"*( JO-NS6, journalist, local daily, Apr. 2008)

This kind of relationship is a global phenomenon and is expected because of reduced funds for public research by respective governments (Waterton, 2005). What is perhaps important is the outcome of this kind of relationship in terms of implication for what would be considered socially desirable practice. Moreover, it is not unusual for researchers to solicit collaborations in pursuit of non-technical gains. A recent study involving Malawian social scientists revealed that Mode 2 researchers engage in consultancies for economic gains and not necessarily to contribute to scholarship through publications (Holland, 2009).

**Researcher-policy-maker relationship:** Alongside the modern biotechnology programme, a regulatory regime was initiated by the government to support biotechnology activities. Scientists in both policy and practice arenas became actively involved as champions in the institutionalisation process. Another kind of unofficial contract gradually emerged between scientists and government. Consciously or

unconsciously, the scientists could influence policy as experts depending on the dynamics of each of the evolving regulatory phases (see Chapter two, section 2.4).

***Researcher-regulator relationships:*** Other contracts were prompted by the granting of approval permits to conduct trials where scientists were obliged to comply with terms and conditions of the approval permit (KEPHIS, 2005; NCST, 2006b). Two official contracts consequently emerged (between NBC and the respective regulatory agencies like KEPHIS and DVS). Through these contracts, specific shortcomings related to institutional infrastructure were exposed which have implications for policy implementation (see Chapter five).

***Scientific community-public relationship:*** Another type of contract was gradually conceived towards the later stages of the biosafety bill debate (phase 3), prompted by the growing tension between pro-biotechnology groups and anti-bill coalition groups. The scientists in policy and practice became increasingly aware that when designing policies that have social concerns, they needed to think about the public and be responsively accountable to them. This culminated into the launch of the National Biotechnology Awareness Strategy (RoK, 2008b) as a platform for engaging the public and other actors in biotechnology related matters.

***Employer-employee relationships:*** All the contracts mentioned above are in addition to the institutional or organisational contracts that the scientific communities get hooked to by the virtue of being employees. These relationships are important because they open up opportunities or space for production and diffusion of knowledge emanating from all the other contracts as well as various knowledge-based nodes (e.g. adhoc coalitions and technological groups).

#### 7.4.4.2 Shifting patterns of behaviour and regulatory roles

Scientists' identities consciously or unconsciously kept shifting in line with the evolution of the regulatory system (through the four regulatory phases) as they tried to accommodate the demands under each relationship described above. In phase 1, there was no argument about the role of contemporary science and contemporary scientists in guiding the regulatory process, even with the presence of donors, as Sander (2007) contends. In the second phase, again the role was clear as scientist experts engaged extensively in guiding the direction of the regulatory instruments with regards to formulation (see also Harsh, 2005). There was a clear boundary between science and policy, with occasional overlaps between institutional, policy, academic and technical practices.

In the latter part of phase 2 and the entire phase 3, there was an evident merger between science and policy, with the process becoming politicised as all players pursued what they perceived to be a legal and desired regulatory regime. The government increasingly relied upon the scientific experts to inform the regulatory policy in terms of resources (scientific knowledge, finances and information). As the data suggest, scientists could reflect on their behaviour and that of others (e.g. NGOs) during this transition. The fourth phase has just commenced after the approval of the Biosafety Act, 2009, perhaps opening up opportunities for engaging public practically and testing the implementation of this particular regulatory instrument.

The experiences of scientists discussed here can be compared to studies that explain the shifts in knowledge production dynamics (Gibbons *et al.*, 1994; Nowotny *et al.*, 2001). Consequently, scientists try to find niches in the emerging cultural spaces of science (Gieryn, 1995: 416) within a dynamic Mode 1 - Mode 2 continuum. From this perspective, the overlaps between science, policy and public represents an empirical

example of changing knowledge-based relationships. This has implications for scientific practice. In trying to adapt to this challenging terrain, confronted by multiple obligations, different identities are inevitably exposed as discussed in the earlier section. These dynamics mimic the findings described by Waterton (2005) and Waterton *et al.* (2001) about UK scientists engaged in boundary science policy related work. Waterton (2005) argues that reduced government funding for research encouraged contract research that demanded different accountabilities (public, home institutions, government, regulator, funding institutions etc). This resulted in diverse forms of science-policy relationships that supposedly shaped the different kinds of knowledge produced by individual scientists, packaged to fit the requirements under each relationship.

This is problematic and as pointed out by Jasanoff (2004b), under contract arrangements, knowledge is “co-produced” and manipulated to fit different applications. Waterton further argues:

*“Variation in co-construction of the science-policy boundary in which scientists play a part means that research questions, resulting knowledge and anticipated outputs are always calibrated together with policy questions, policy knowledge and policy understanding of what constitute acceptable outputs.”* (Waterton, 2005:439)

This shift in identities is also described by Gibbons *et al.* (1994), claiming that scientists may adopt shifting social identities in research to attract funding. They argue that what is needed to play this game is the ability to move back and forth between environments. However, questions emerge as to how easily this can be navigated and what the implications might be and it can be problematic as others have noted. For instance, Guston (2001) alleges that, what these conflicting science policy knowledge production efforts do is create tension and put a strain on the behaviour of scientists. Though Guston does not explain the nature of this tension, it can be either negative or positive for policy as illustrated by the current empirical case. This is because, as stated

previously, there are different kinds of obligations (or accountabilities) with varying interests demanded by each relationship (Waterton, 2005).

#### **7.4.4.3 Implications for theory and practice**

A Mode 2 research environment seems to be problematic for the scientific community but it is unclear how actors should confront the ensuing strain. For instance, what Mode 2 practice fails to reveal in the regulatory context is the dynamism and activism portrayed by actors (within the scientific community) in the pursuit of a desired regulatory regime driven by particular motivations that could be value or interests based. This activism is manifested corporately reflecting increased togetherness, with principles different from those of transdisciplinarity and integration. These principles as understood in Mode 2 context may work perfectly under a research environment towards technological development.

As others have noted (cf Jasanoff, 1987), this current research suggests that scientific values (for example interests, scientific goals, protection of contract relationships) and politics play a significant role in the learning dynamics experienced in a regulatory context, perhaps more than a technological context. This is also consistent with the claim by Murphy and Chataway (2005) that economic and social differences interplay in the articulation of environmental policies. Although their focus is at international and regional level, same issues intensify at domestic level as this research suggests, perhaps more significantly. This may partly be supported by the seemingly close interconnection between dynamics of knowledge production and use, and the stage of biotechnology products development. In the early stage of product development (like in the case of developing countries), efforts towards regulatory policy innovations may supersede economic efforts although in the case of Kenya the two have co-evolved.<sup>195</sup> But that is

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<sup>195</sup> More research may be needed to generalise this claim.

not to say that regulatory innovations and technological innovations are unrelated. On the contrary, the two are iterative and highly dependant on cumulative learning of social and institutional actors, and the relationships built around this, as implied by innovation systems literature (see Chapter three, section 3.4.1).

Kenya's science and technology policy for a long time has been structured in such a way that scientists pursued research as a public good (Odame *et al.*, 2003). This may be synonymous with Mode 1 research which indirectly impacted scientific practice and consequently the regulatory practice. It was emerging that scientists were struggling to conceptualise the new regulatory demands without putting much effort to change their normative and rigid scientific thinking and behaviour. This suggests that some scientists are still grappling with Mode 1 behaviour as Mode 2 knowledge production dynamics confront them through biotechnology innovation. This may imply that the biotechnology innovation system is a good platform for analysing Mode 2 principles as alluded to by Odame *et al.* (2003). Similar struggles of identity and related practice in a transdisciplinary setting was reported by Lenhard *et al.* (2006:345) who in their empirical research on structural change in disciplines found that "old loyalties are fiercely maintained while new identities are created". This observation is also shared by Nowotny *et al.* (2003) who argue that scientific behaviour is modified to accommodate the Mode 2 sciences and old normative practices continue to be experienced.

Perhaps this poses a fundamental question related to quality of knowledge "co-produced" to suit a particular context. Context as implied by Mode 2 proponents tends to take as given knowledge that is produced with users in mind such that at the end of the day, it would be socially desirable. However, scholars advocating socially desirable public participation, risk evaluation and risk communication models in the new life sciences have warned against the decreasing credibility of scientific knowledge in

informing environmental policies (cf Jasanoff, 1987, 2003). Reflexivity is what is supposed to safeguard against this through what Nowotny *et al.* (2001) call re-conceptualisation of knowledge. This again calls for learning in order to acquire “multi-layered skills” that cater for critical reflexive capacity needed to engage with divergently different interests and values (Lyll and Tait, 2005).

#### **7.4.4.4 Lessons and conclusion with respect to shifting behaviour**

On a positive note, what Mode 2 science seems to be doing in the Kenyan context is to make scientists refocus their thinking towards a broader view of science. Firstly, the need to protect knowledge (patents) has been emphasised, albeit a slow change. The following quote from a university professor who at the time of field work was engaged in science-policy work as a chair of the NBC explains the knowledge dynamics occurring in Kenya:

*“We scientists are not used to these elaborate [regulatory and patenting] procedures. For example on the area of patenting, scientist see it as a bother. Even now I have a letter saying please ensure you protect your research findings. Because many of us find it as a bother, just to go to the Ministry of trade to collect the patents application form and filling it. One; Kenyan research has always been public research whereby you are doing it for the public with no expectation of reward from that. It is a culture because we have been doing public research for the purpose of publishing and we do not see economic returns from that. Kenya is not used to patenting of their research. Scientists are used to public research for free. You are only thinking of publishing this nice paper and get promoted. It is quantitative research rather than qualitative research. Qualitative research is when you aim at getting a product and as me here when I want to publish, I need three papers and I become a full professor; that's it. Now we have to create awareness among research institutions because the problem is that, they are not aware. Even in KARI, despite the fact they were involved in all these GE processes, implementation [protection of research findings] is difficult, they look like they have never heard of that.” (ATp-PS3, technological & biosafety policy advisor, public university, Nov. 2007)*

Secondly, engagement of scientists in the formulation of regulatory instruments, (particularly the biosafety bill) that sparked public controversies made them re-think the social implications of scientific practice and perhaps the resulting policies.



Overall, what the current study seems to suggest is that a Mode 2 working environment is too demanding for scientists (both in practice and policy) characterised by the increased and dynamic pace in technological, institutional and regulatory policy innovations. In trying to navigate their way through the unprecedented institutional changes, the scientists have been challenged by many exogenous and endogenous factors resulting in their devising coping strategies. The shifts in cultural practice demonstrated empirically challenge Mode 2 principles which could not account for non-technical factors that shape the behavioural practice linked to the regulatory practice. Knowledge produced for the purpose of influencing the regulatory instruments could also not be accounted for.

The dynamics occurring here can be partly explained through analysing scientists holistically within the “communities of practice” or “epistemic communities” based on the different roles they play within these groups as described elsewhere. The former as advanced by Johnson (2007), although applied in the context of development, explains the role of learning and knowledge production in a dynamic and often complex social setting, particularly if conceptualised as “action learning spaces” (Johnson and Wilson, 2006). The conceptualisation of learning and knowledge production through the lens of epistemic communities (Haas, 1992) on the other hand provides understanding of scientific practice in a policy context. This concept is revisited further below as learning, knowledge and policy influence are explored in the next section through the lens of policy coalitions.

#### ***7.4.5 Influence of regulatory policy through policy coalitions***

Biotechnology and biosafety arenas are important spaces where the heterogeneous scientific community converged to consolidate support for their visions and views about the regulatory process and policy. Within these spheres, they seem to have shared norms and beliefs with regards to GE technology and desired regulations to a certain extent,

thereby behaving like an epistemic community. However, there is a striking difference in the way beliefs and values were shared in a regulatory context as described through the lens of advocacy coalitions (AC).

#### **7.4.5.1 Advocacy Coalitions Framework (ACF)**

Efforts by both scientist and non scientist communities to influence regulatory policy, particularly the biosafety bill occurred within informal advocacy coalitions. This qualifies governance of biotechnology in Kenya as having elements of unstructured procedures (Harsh, 2005). This deduction is derived from analysis of the regulatory policy subsystem and its actors as it evolved for about 2 decades with increased tension and conflict during end of regulatory phase 2 and entire phase 3. This tension is anticipated to continue in phase 4 as the new Biosafety Act, 2009 enters the implementation phase. This analysis is presented here using features of ACF (see Chapter 3, section 3.4.4).

***Kenyan regulatory policy subsystem scope and actors:*** The scope is defined by innovations in modern biotechnology and actors implementing the various regulatory instruments. The actors comprise government players, academics, researchers, journalists, legal officers, farmers, consumers, media, NGOs in the biotechnology arena, civil society among others (see Appendix 5). The heterogeneous group of scientific community selected for this study form part of this scope.

***Coalition members:*** Data identified two rival coalitions. The dominant one comprised of a large group of scientists from the policy, practice and pro-biotechnology NGOS, their respective institutions and some members of parliament. The minor coalition comprised of members from the civil society, media and some members of parliament.

**Policy core beliefs:** The interviewees were polarised in their preferences for a biosafety bill. Some supported the bill due to its potential to enhance GE technology deployment while others felt the bill would promote responsible science. Some members of civil society supported the bill for its potential to enhance public protection through legal controls while others were totally opposed to it. There were other differences in policy beliefs expounded in details in Chapter five and perhaps which explain the ambivalences in the nature of biosafety regulations different groups of scientists seemed to detest or prefer (enabling, constraining, permissive, restrictive or cautious).

#### **7.4.5.2 Analysis of Kenyan regulatory policy subsystem**

The ACF predicts that membership of a coalition and policy core beliefs remain stable and can be useful in identifying impediments to policy resolution in the formulation of the biosafety bill (Sabatier and Weible, 2007). Critical analysis of the regulatory policy subsystem during the evolving regulatory phases exposes different groups with different political interests who could negotiate core values and beliefs based on the concern or conflict at hand (Sabatier, 1993). The biosafety bill conflict therefore separates different coalitions based on the different core policy beliefs. In this particular case, the legalisation of regulations through enactment of the bill for management of biotechnology was the concern at hand.

Scientists both in the practice and policy arenas stood to gain from a regulatory policy that would enhance their scientific and policy ethos (a view expressed by many interviewees). As shown in Chapter six, there was a blurred boundary between pro-biotechnology “scientists” and “policy makers” that qualified them to be proponents especially in pursuing the temporary shared belief (bill for management of biotechnology). Consequently they viewed the “non-scientific public” as non-supportive of GE technology (resisting and fighting the biosafety bill was perceived to be a

rejection of this technology). This consensual view of the bill portrayed by the scientific community (though for different reasons) denotes a shared belief. Thus, as mentioned previously, analysis of the data identified two competing coalitions<sup>196</sup> (opponents and proponents of the biosafety bill). The opponents (civil society) presented a competing counter coalition. The two coalitions influenced the regulatory policy subsystem in various ways.

### *Use of resources:*

The pro-bill coalition utilised resources in the following ways:

- The policy players happen to have legal authority to coordinate and direct the policies placing them at an advantageous edge over the opponents. NCST for instance directed the policy initiatives under the legal mandates of the Science and Technology Act, (RoK, 1980 & 1982) and the interim biosafety regulations (RoK, 1998).
- In knowledge intensive subject like biosafety, scientists in practice and Non State Organisations (NSS/NGOs), who happen to control scientific resources, played a key role in provision of technical and scientific information. The Hand Book for Policy Makers (2007) is evidence of a combined endeavour between policy players, research scientists and NSS actors.
- Scientists affiliated to pro-biotechnology NGOs command substantive amounts of finance directed towards policy, technical and biosafety research. They were extensively linked to most policy and biotechnology fora, and activities organised during the period under analysis (Appendices 5, 6, 7 & 9).

The anti-bill coalition on the other hand utilised resources in the following ways:

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<sup>196</sup> Stakeholders within a coalition are like-minded people who may include researchers, journalists, legal officers and government officials. They share basic values and search for means to accomplish them. They also tend to over-emphasise the influence of their opponents (Sabatier and Weible, 2007; Sabatier and Jenkins-Smith, 1993).

- It commanded considerable amount of finances.<sup>197</sup> The increased media reportage (see Appendix 9) may suggest increased finances and mobilisation of a wide range of civil society actors, thus strengthening the coalition. Initially the coalition had 7 members (Harsh, 2008) but the number grew to 12 (Action Aid, 2004) and later to over 30 as of 2008 (members of the Kenya Biodiversity Coalition-KBioC).
- This coalition seemed to have public support through the orchestrated activities of the established and popular members [e.g. Action Aid financing their activities, Kenya Organic Farmers Association Network (KOAN) representing organic farmers, Consumer Information Network (CIN) representing consumers and Kenya Federation of Agricultural Producers (KENFAP) representing farmers]. They therefore used the public as a resource.
- Different members of this coalition had access to environmental groups<sup>198</sup> and were also privileged to access “reliable” scientific information.<sup>199</sup>

**Available venues:** Venues are institutional arenas within which stakeholders have the opportunity to influence policy-making (Weible, 2007:96). The pro-biosafety bill coalition was active in various venues facilitated by the pro-biotechnology fraternity and the government {conferences, workshops and government institutions like NCST, KEPHIS, NBC and media}. Parliament was another venue in which both coalitions actively engaged the parliamentarians. This is evidenced by two counter parallel bills tabled in parliament by each of the coalitions (biosafety bill 2008 from the dominant

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<sup>197</sup> Interviews with NGOco-NS4 and NGOof-NS1 indicate that at the early regulatory phases funds were limiting their activities but later they were able to consolidate enough finances to counter pro-bill groups.

<sup>198</sup> During field work, interviewee NGOof-NS1 disclosed that the KBioC coalition members had received training from green peace officials on advocacy.

<sup>199</sup> One interviewee who is a molecular scientist offered valuable scientific advice to this coalition (he was that important that an interview I had arranged with an official from one environmental NGO could not commence without him being present). He was also purportedly linked to some scientific aspects of certain media reports originating from the civil society through this coalition as disclosed by a journalist interviewee (JO-NS6).

pro-bill coalition & the biotechnology and biosafety bill 2008 from members of the minor biodiversity coalition). The court was another venue used by the anti-bill coalition (a confidential document obtained during field work is proof of this litigation act).<sup>200</sup> The public is another institutional venue, operationalised by the anti-bill coalition through demonstrations to amass public and political support.<sup>201</sup> The media was another space used extensively by both groups (see Appendix 9).

#### 7.4.5.3 Policy learning and influence

How was policy change achieved in the Kenya's regulatory policy subsystem? This question is central to this thesis because the second research question sought to explore how the scientific community may have influenced the development of regulatory instruments. This section is discussed from that context. Three factors based on Sabatier's framework can cause learning and belief change: external shock, policy oriented learning and a hurting stalemate (Sabatier and Weible, 2007) and are explored below in relation to Kenya.

*An "external shock"* is likely to change components of policy core beliefs. In the Kenyan scenario, the over-emphasised potential of biotechnology applications to address food insecurity impacted actors' re-conceptualisation of their stances towards, for instance stringent regulations. This approach to regulation made pro-regulatory policy advocacy coalition to argue for pro-innovation regulatory policy (permissive or facilitative) in order to enhance economic competitiveness, presumably for the benefit of the poor. The initiation of the biotechnology programme in early 1990's through the sweet potato and rinderpest vaccine projects gave a new thrust to the hyped

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<sup>200</sup> This was also corroborated by JO-NS7.

<sup>201</sup> Interviews with RSIn-GP2, NGOcs-NS3 and NGOco-NS5.

biotechnology innovation and emerging regulatory policy subsystem that commenced with the drafting of first regulations.<sup>202</sup>

The general elections towards the end of 2007 may be seen as another external political shock. Most actors linked this shock to the premature halt of efforts by the pro-bill coalition group to push for the enactment of the bill just before the parliament was dissolved to pave way for the election campaigns.<sup>203</sup> Similarly, the dissolution of parliament was seen as a “divine intervention from God” by the members of the anti-bill coalition, which prevented approval of a purportedly flawed bill.<sup>204</sup>

*Policy oriented learning* may be analysed relative to the one and half decades that the subsystem has been co-evolving alongside the biotechnology programme. During this period, there has been an incremental accumulation of scientific and policy information. Policy learning has presumably been gradual and incremental as the scientific community engaged in biotechnology and biosafety activities and as they dealt with challenges and conflicts during implementation of the interim regulations. Learning was also enhanced through the heterogeneous knowledge-based nodes like the adhoc Kenya Biosafety Coalition Network (KBC) fronted by the scientists and KEGCO or KBioC groups fronted by the civil society. Influence of policy may be linked to the legalisation of the biotechnology activities and the biosafety regulatory regime through the enactment of Biosafety Act. The Act emerged and replaced the previously official “no commercial GMOs” policy that many interviewees interpreted as ineffective, paving way for a balanced policy approach to safety and development.

The policy learning impacted the shifting perspectives and beliefs of actors over time. However, productive learning could have been constrained by possible instances where

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<sup>202</sup> Interviews with PRp-PS4, RSPu-PS8, TAN-NSS2, RSPu-PS7 and RSIn-GP9.

<sup>203</sup> Interviews with RSIn-GP2, TAN-NSS2, TAR-NSS1 and BIp-PS13.

<sup>204</sup> Interviews with NGOf-NS2, NGOco-NS4 and NGOf-NS1.

actors may have despised or rejected conflicting or threatening information coming from opposing groups. This would enhance a socially desirable balanced view making it a legitimate process.

*Hurting stalemate* is a situation in which all parties involved in a dispute view continuation of the status quo as unacceptable and run out of options and venues to achieve their objectives (Sabatier and Weible, 2007). Two interpretations may be drawn from the Kenyan case. Firstly, the anti-bill coalition may have succeeded in curtailing the efforts of the pro-group in pushing for the enactment of the bill but this was only temporarily. It may also have weakened the position of the pro-bill coalition and perhaps strengthening opportunities for an “all-inclusive coalition” that could be emerging in the post-bill or post-Act era. When a stalemate was experienced during regulatory phase 3, various attempts to engage the opponents may be construed to be consensus-based efforts towards dealing with the stalemate.<sup>205</sup> At the same time, the BioAWARE was launched to integrate the voice of the public in the deployment of GMOs (RoK, 2008b). Secondly, the bill was eventually promulgated into law on Feb. 2009 (RoK, 2009). This may be construed to be victory for the pro-bill coalition. The Act is a product of a prolonged conflict between the pro-bill process group and the anti-process group.

It is again too early to tell whether the coalitions will experience a hurting stalemate during the implementation of the Act. Analysis of the policy subsystem makes it possible to offer policy recommendations that may facilitate effective implementation of the Act and related technology transfer (Chapter eight).

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<sup>205</sup> The opening remarks by interviewee ARBp-PS16 from a public university who was moderating a stakeholders' workshop between pro-bill and anti-bill groups appealed for both groups to work together towards a common agenda, the deployment of biotechnology for economic usefulness (NCST, 2007).



#### **7.4.5.4 Conclusion and implications with respect to policy coalitions**

Using the principles of policy coalitions, the current study has empirically demonstrated dynamism in advocacy coalitions formed around regulations implementation, and how resources and belief systems interplay to influence policy learning and subsequent policy change. These findings resonate with Weible's (2005, 2007) who demonstrated how policy core beliefs and resources interplay in influencing formulation of a conflict laden subsystem in USA {in Weible's case, the Marine Life Protection Act (MLPA)}.

Members within advocacy coalitions are able to adapt to challenges and opportunities through learning in order to realise their goals. The intense coordination and relationships building of like-minded players with respect to both coalitions (opponent and proponent) supports the policy core belief concept that drives the sustainability of advocacy coalitions as asserted by Sabatier and Weible. How the game was played out defies the coalition principles related to policy learning, beliefs and consequent policy change. How is it possible then that policy scientists behaved more like an interest group by interacting with actors of similar beliefs (with respect to the biosafety bill) rather than with a mix of players representing all interests? Although this behaviour supports advocacy coalition principles where government agencies can be members of coalitions, shared beliefs fail to explain explicitly the dynamism of the policy learning experienced particularly during regulatory phase 3.

The strategies used in the Kenyan subsystem exposed high level relationships building and persuasion in an attempt to enlist members who could support their policy beliefs. This persuasion is tantamount to influence, which is not given adequate space by AC approach (this research study was not testing this theory). This however has both positive and negative implications. Firstly from a positive view, this may have triggered faster approval of biosafety law perceived to have taken shorter period than other

agricultural policies.<sup>206</sup> Approval of the Act has indeed opened up a new era for technology transfer through deployment of products of GE technology, which may be good for the country economically (perception held by many interviewees).

Secondly from a negative view, the approved regulatory policy may be perceived to be lacking non-scientific or public input. For instance information (or knowledge) within the pro-biosafety bill advocacy coalition was predominantly sought from allies within the same coalition (policy makers relied upon researchers and NGO scientists) who were members of the same coalition. This may impact the Biosafety Act implementation, having not received wider public scrutiny or input.

## **7.5 Other tensions related to regulations and regulatory practice**

Previous sections have shown that various challenges confronted scientists as they tried to adapt to new ways of research and policy. In the process, two main tensions emerged related to communication and regulatory compliance. This section analyses these tensions in reference to various theoretical perspectives used in the entire chapter.

### ***7.5.1 Poor and constrained communication***

What is indisputable in the current study is the importance attached to value of communication (about risk and GE technology) by many interviewees, at least to change the negative public opinion. However, productive communication on the part of scientists was constrained by fear of misinterpretation and exogenous pressures, hence the biased reporting inclined towards benefits. This can be interpreted in various ways.

#### **7.5.1.1 Exogenous pressures**

Biased or impartial reporting was aggravated by pressures from different accountabilities (for instance, donors require reporting to be done in particular way, the

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<sup>206</sup> Interview with TRTp-NSS3 when making a comparison with the seed policy.

NBC require reporting to be tailored according to the GMOs application form; KEPHIS requires monitoring and inspection reports in accordance with the compliance forms). This exposes the strain of communication as scientists navigate the Mode 1 - Mode 2 research terrain discussed previously. A similar strain in reporting was experienced by UK scientists as they tried to adapt to new research environment that supported contract research (Waterton, 2005). Waterton observed that, scientists found it easier to produce reports for fellow scientists since they are scientific reports as opposed to project and policy reports. The latter are negotiated, thus, scientist become “co-producers” of knowledge together with their “customers” (*Ibid*,:439). If the customers reports are difficult to write, what about public reports that have not been negotiated?

#### **7.5.1.2 Challenges in risk communication**

Fear of misinterpretation and misreporting, and distortion of scientific facts (by public and activists) could also be explained by the uncertainty linked to GE technology and perceived risks. Proponents of public participation theories have cautioned against different repercussions of adopting a technical approach to risk regulation and disregarding public in governance of risky innovations like biotechnology (cf Levidow, 2007). What scientists may not realise is the importance of risk communication (amongst all stakeholders) as a key component of risk analysis and risk management (Keese and Meck, 2006). According to Keese and Meck, based on their experiences in the Australian GMOs regulatory practice, knowledge (information) sharing can have an undue influence on the outcome of regulatory disputes.

#### **7.5.2 Non-compliant regulatory practice**

This practice may be interpreted in two ways. Firstly, the regulatory instruments were weak in achieving the pro-innovation agenda and secondly, the policy targets have a negative attitude towards regulation.

### 7.5.2.1 Weak regulatory instruments

The instruments providing benchmark for regulations implementation were perceived to be ineffective based on the agenda of the innovation communities. As earlier reported regulatory instruments (particularly for field trials) were perceived to be restrictive, bureaucratic and lacking clarity.

Constraining policy instruments can have negative impact on innovation based on mode of operation as expressed by GE scientists in USA and Europe (Rabino, 1994). Through this study, Rabino showed that strict government regulatory control results in increased regulatory pressure, that reduces competitiveness (*Ibid*,:44). Others like Chataway *et al.* (2006) through the accounts of industry managers and policy makers were able to categorise biosafety regulations based on whether they are enabling or constraining in achieving the intended purpose.

Besides delaying innovation, constraining or restrictive nature of regulations has other ethical ramifications as this thesis shows. It demoralises researchers, impacting upon a responsible and ethical regulatory practice, as expressed by an interviewee from an international organisation:

*"What this thing [bureaucracy] end up costing is, it makes scientists do things on the back door. I am sure if you ever did a survey in this country you would be so shocked at how much the scientists are doing and the regulators have no idea that those things are happening. But when the system is bureaucratic the scientists will not stop doing their science. If you think the regulators will be hard on this, they just learn to loop around the regulation and continue doing their thing because for them, they have to continue doing science and continue publishing."* (RSIn-PS6, general health & safety advisor, IRI, Nov. 2007)

Based on this analysis, regulations may promote both innovative and unethical behaviour, issues that all actors including regulators need to be aware of. On the other hand, the government must factor these conflicting aspects into their policies and enforcement mechanisms. Perhaps this is the reason why scholars in governance

theories related to life sciences differentiate between the “government” and “governance” approaches to regulation (Tait *et al.*, 2006). The former aims at promoting ethical behaviour (sometimes oblivious of implications), while the latter promotes innovative policies based on evidence-based interests and values of multiple actors.

#### **7.5.2.2 Attitude of scientists**

Evidence from this study suggests that scientists in practice have a negative attitude towards regulation and regulators. Irwin *et al.* (1997) in a study investigating agrochemicals regulation in Britain observed similar negative attitude by scientists towards regulation. In Kenya, this attitude is linked to the cumbersomeness in complying with terms and conditions set out in the regulatory instruments. This notwithstanding, what scientists do not seem to realise is that GE technology is highly regulated as well as knowledge intensive, perhaps more than the basic research they are used to. Irwin *et al.* (1997) argue in this respect that, regulatory compliance is a major challenge for the institutions concerned *as well as the individuals involved* (emphasis added). Regulatory practice is however different from normal basic academic practice. As Jasanoff (1990: 80) asserts, in an academic environment, science is undertaken with a view of advancing knowledge. On the other hand, regulatory practice is bounded by exogenous pressures of “time, politics, directed towards closure, proprietary, subject to a variety of types of review and undertaken with an aim of aiding policy-making”. It is also institutionally and culturally embedded (Irwin *et al.*, 1997). These factors evoke strain on the part of the scientists and may lead to accountability and transparency compromises.

#### **7.5.3 Conclusion with respect to emerging tensions**

It was emerging that the Kenyan scientists are still grappling with the rapid technological and institutional changes characteristic of Mode 2 and they are still

holding Mode 1 values (pride, individualistic, optimistic thinking as described by the interviewees). These values seem to affect the process of adaptation towards an integrated behaviour, at least with respect to science communication and regulations compliance.

With respect to transparency in communicating different aspects of GE science, the increased demand for accountability and the informed public demand reflexivity on the part of scientists. This is in line with the demands of Mode 2 research that call for reflexive and socially desirable practice at least with regards to knowledge sharing and dissemination (Nowotny *et al.*, 2001).

With respect to regulatory practice, regulations or standards in Mode 1 research have been just the basic good laboratory practice while in Mode 2 research, the additional biosafety regulation demands accountability to a wider stakeholder (government, regulator and public). However, as Rothstein *et al.* (1999) note, requisite regulatory compliance comes with challenges like regulatory capacities. This could also work against regulations implementation, hence impacting compliance negatively and indirectly. In Kenya, capacity had been identified as a challenge in risk assessment and decision-making processes.

Regulatory behaviour related to regulations compliance challenges what is expected under Mode 1 and Mode 2 research scenarios. Behavioural change is inevitable towards a compliant practice (on the part of practitioners) and enabling regulations (a role for the policy scientists). This is a challenge since regulations are designed to address broader societal issues (safety, quality, economic, technological). Perhaps this is the reason why a number of scholars have emphasised rethinking of regulatory practices, towards a “smart regulation” without undue strain to innovative practices as well as consideration

of the local context under which the regulations are implemented (Tait *et al.*, 2007; van Zwanenberg *et al.*, 2008).

## **7.6 Regulatory practice and influence of regulatory instruments**

Data from this study suggest that the scientific community influenced the regulatory regime trajectory. The influence was articulated through learning, and generation and utilisation of knowledge as discussed in this chapter. But equally important are the interests and values revealed empirically through the current study. Shared beliefs and intense negotiation achieved through policy coalitions explained the activism portrayed by the scientific community in the Kenyan regulatory policy subsystem. As discussed above, resource was a driving force but perhaps what is clear is that the beliefs were only shared for a particular purpose and agenda (lobbying for the enactment of the bill that purportedly was in favour of the different interests of actors).

Influence can be interpreted from the perspective of use of expertise discussed previously through selection of knowledge used to inform the decision-making processes. Such form of expertise has been found to lack legitimacy based on its impact on the outcome of science policy deliberations, for lacking wider public input (Levidow and Carr, 2007; Weingart, 1999). To legitimise the decision-making process, a democratic expertise as Nowotny (2003) asserts, should involve a wider group of experts outside the technical or scientific arena. This being the case, the Kenyan process can be viewed largely as having excluded the wider stakeholder, particularly in the formulation of the Biosafety Act. This is a positivist or narrow usage of knowledge that some scholars have criticised arguing that it is politicised and assumes that expert knowledge is objective and rational in guiding policy-making (Levidow, 2007; Weingart, 1999).

Despite these clear aspects of influence in terms of regulatory direction more generally, critical analysis of the Biosafety Act seems to address many of the concerns raised by interviewees. This may be viewed as positive influence of the content commensurate with the concerns of the scientific community. However, there were other views that any potential efforts to influence the outcome of the bill to accommodate unwarranted interests were thwarted through various national regulatory and policy checks. Notwithstanding, this is not to say that the regulatory instruments particularly the Act (RoK, 2009) are acceptable regulatory documents.<sup>207</sup> Moreover, real test will occur during phase 4 of the regulatory process in the actual implementation of the Act as societal issues become real with the actual commercialisation of GE products.

## **7.7 Chapter conclusion and summary**

Through insights and lessons drawn from the wide body of literature (science policy, theories of knowledge and learning, innovation systems and policy coalitions), the foregoing data analysis suggests that, the regulatory policy innovations occurring alongside the overall biotechnology innovation system transition were somewhat bounded up in the broader knowledge production dynamics associated with the latter. As presented by proponents of Mode 2, knowledge production in a broad sense is generally linked to institutional innovations. However, knowledge produced in the regulatory context as illustrated in this thesis is relatively different in terms of institutional and cultural aspects. It emanates from relationships built around disciplinary, professional and policy knowledge-based groups. As much as it is technical in nature, it reflects to an extent values and cultures of these groups. This challenges application of most knowledge production theories with regards to regulations implementation. Table (11) below summarises these challenges and implications, and because this thesis does not stop at that, the implications are explored

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<sup>207</sup> Research should be done to establish this claim targeting a wider group of stakeholders outside the scientific community.



further in the next chapter with a view of providing some policy recommendations for improving scientific and regulatory practice.

**Table 11: Summary of interpretation of raised issues in the context of knowledge dynamics**

CHAPTER SUMMARY		
Issues	Interpretation	Conclusion/implication
Divergent perceptions of regulation & regulatory practice framed in terms of GE prospects & related risk	Historical background of GE introduction in Kenya and the broad risk approaches to regulation support these views.	These expose a narrow approach to regulations implementation based on the imbalanced debate about benefits and risk.
	Scientific and social values held by scientists in their heterogeneous knowledge-based groups are exposed.	With respect to regulatory policy processes these distinctions reflect different beliefs and values that characterise different cultural spaces that scientists occupy.
Behaviour and role of scientists in regulatory process & instruments	<ul style="list-style-type: none"> <li>-Scientific community proactively engaged in regulatory activities as experts, a role presented by different learning opportunities and motivations at individual and corporate levels.</li> <li>-The pursuit of desired regulatory regime was articulated effectively within policy coalitions &amp; relationships built over the years during technological revolution.</li> <li>-Regulatory activities through different types of knowledge produced directed the regulatory trajectory.</li> </ul>	-Policy coalitions complement Mode 2 in exploring the political and social factors that underpin the forms of knowledge produced in a regulatory and political context and the impact on policy change.
Scientific & regulatory practice	<ul style="list-style-type: none"> <li>-The two are embedded in the broader institutional and actors' shifts in cultural practices from Mode 1 to Mode 2 research, characterising a dynamic innovation system in transition.</li> <li>-Different behavioural features exposed during implementation of regulations triggered by different endogenous and exogenous pressures that accompany biotechnology innovation.</li> </ul>	<ul style="list-style-type: none"> <li>-The ensuing requisite institutional and behavioural changes cause tensions and strain during regulations implementation reflected through shifting social identities.</li> <li>-Mode 2 fails to capture sufficiently shifts in cultural practices and the underpinning factors driving the involved actors. These factors include nature of relationships, values and interests.</li> </ul>

### 8 Conclusions and recommendations

#### 8.1 Introduction

This research project aimed at analysing, understanding, and describing practical aspects of implementation of biosafety regulations in Kenya through the lens of the scientific community. The thesis has identified the nature, content and form of knowledge produced and used in regulatory context, and its impact on biosafety policy-making. Further, it has sought to know what this dynamic of change in knowledge mean for regulatory instruments and the broader biotechnology innovation system.

The general theoretical literature on governance of modern biotechnology and specifically in the context of Africa is inconclusive on several vital questions within knowledge production discourse (cf Harsh, 2005; Sander, 2007; Lyall *et al.*, 2009a). To explore this gap, this study set out to answer the following research questions:

1. What are the perspectives of scientists on the implementation of biosafety regulations and why might they be holding these views?
2. Have the practices of scientists related to implementation of biosafety regulations shaped the evolution of the regulatory process and if so how?
3. What is the implication of the scientific practice on the biotechnology innovation policies and knowledge use?

The main objective of this research was to explore how governance of modern biotechnology through biosafety regulation may be improved for efficient deployment for economic use.

To synthesise the empirical data generated in the process of tackling these questions, this chapter is organised as follows: a summary of the findings is presented first,

followed by a synthesis of the theoretical and policy implications. Following this, practical policy recommendations and lessons are explored in the light of knowledge use and how best regulations can be implemented for enhanced pro-biotechnology innovation governance and deployment. The subsequent section explores suggestions for further research, ushering in a discussion of limitations of this study. Lastly, the chapter concludes with an epilogue.

## **8.2 Synthesis of empirical findings**

The main empirical findings were theme specific as highlighted by each empirical chapter. The different regulatory phases during the co-evolution of regulatory system and the biotechnology innovation system are illustrated in Chapter two. This set the background and the context for the study. The views of scientists on regulations and regulatory practice are presented in Chapter five while the behaviour and role of the scientific community in influencing the regulatory process is outlined in Chapter six. In Chapter seven, the theoretical and empirical explanation of the data is undertaken.

Synthesis done in this section endeavours to show how the three research questions were addressed and the conclusions that were drawn.

### **8.2.1        *Perspectives of regulations and regulatory practice***

In this sub-section, data synthesis is done to show whether and how this first research question was tackled: *the perspectives of scientists and the reasons behind the held views*.

Perceptions related to risk assessment (RA) and regulatory decision-making processes brought to the fore weaknesses and strengths of the main regulatory instruments and institutional structures. For instance, the instruments that guided biotechnology research prior to Biosafety Act (2009) were constraining both science in terms of progression

and scientists in terms of scientific and regulatory freedom. Besides these institutional weaknesses, this study identified non technical aspects that hampered the regulations implementation process. These include values and interests that largely explained and supported the reasons behind the perceptions of scientific community regarding nature of regulatory instruments and practice. These social factors further explained many regulatory actions undertaken by the scientific community towards achieving their desired regulatory regime.

A general agreement that biotechnology innovation offers prospects for improved agricultural production was a driver for scientists and accompanying institutional changes. Thus, regulations were viewed in terms of providing space for technological advancement. This reflects the interests and values the scientific community attach to GE technology. This is consistent with the narrow view of the technology as an outright solution to agricultural production constraints (Hisano, 2005) and is in line with the historical developmental background upon which GMOs introduction in developing countries is based {to address food production constraints (cf FAO, 2004)}. Further, perceptions about risk placed the scientific community into proactive and reactive groups reflecting the values they attach to risk. These stances are not dissimilar to discourses about risk regulation discussed by various scholars and which are linked to risk perceptions (cf Tait and Levidow, 1992; Dunlop, 2000).

One unique feature about the current study is that the perceptions of scientists evolved and changed over time along the different research stages and regulatory phases. This was due to incremental learning and influence of different relationships built over time.

### ***8.2.2 Role of scientists in shaping of regulatory process & instruments***

In this sub-section, implications of shifting perceptions and related practice is synthesised to show how the second research question has been addressed in this thesis: *how scientists shaped the evolution of the regulatory process and instruments.*

Through individual based and institutionalised roles in the regulatory process, evidence presented in this thesis shows that, the scientific community influenced the evolution of the regulatory process. The study further suggests that scientists are not disinterested actors in the regulatory instruments formulation process, and are inspired by different motivations and interests. Perspectives related to the different activities they engaged in based on different interpretations, reflect varying and shifting cultures ranging from academic, research, practice, policy, economic or civic.

Scientists seized the opportunity to influence the regulatory process as experts producing different kinds of knowledge and disseminating it in diverse ways. One way they used this expertise is through persuasion of key players in regulatory decisionmaking processes and enactment of the biosafety bill. This is however expected in technically and politically charged biosafety regulatory policy process (Scoones, 2002; Newell, 2002). This notwithstanding, one distinct observation in this study is the institutionalised nature of approach to regulatory process and particularly in the formulation of the bill. A pro-bill group that comprised of both public and private figures came together in their persuasion efforts to lobby for the enactment of the bill. This has implications as discussed further below.

As much as the influence of outcome of the regulations was empirically demonstrated driven by varying interests, some interviewees claimed that counter activities by opponents, political controls and credibility of scientists minimised the potential

influence of the content of the regulatory instruments and outcome of regulatory decisions.

### **8.3 Theoretical and policy implications**

Various implications for practice and policy are synthesised to support the third research question: *the implications of scientific practice for innovation policies and knowledge use.*

#### **8.3.1 Theoretical contributions**

##### **8.3.1.1 Mode 2 and regulatory knowledge**

The findings suggest that, the perspectives of the scientific community taking part in this research are much more complex than can be explained by simple institutional challenges that confront them as they implement regulations. This complexity is reflected in the accompanying regulatory practice that reflects a subtle deviation from the normative scientific practice. In addition to institutional dynamics reflected in Mode 2 knowledge production, implementation of regulations exposes cultural dynamics characterised by changing behavioural patterns. This is revealed empirically as the heterogeneous scientific community reacts and consequently adapts to new institutional changes brought about by the reorganised role of knowledge in a changing multifaceted and multiple actor biotechnology innovation and regulatory terrain. However as they adapt, they exhibit particular behavioural practices that are commensurate with the cultures of the disciplines, professions and knowledge groups they belong to. In addition, relationships built over the years during professional progression provide a means through which scientific behaviour is impacted. The ensuing shifting social identities pose many questions that relate to the implications for biosafety regulatory instruments and social accountability to the wider public.

This has brought a new perspective of looking at knowledge production and use. From this study, it can be concluded that knowledge produced in a regulatory context is value-laden which is consistent with what other scholars have reported (Jasanoff, 1987, 2003; Murphy and Chataway, 2005). It is also culturally embedded and depends on relationships build around different cultural groups, particularly professional relationships (Haas, 1992, 2004). These factors ultimately affect how it is eventually used for policy and technological purpose.

As the literature suggests, the way Mode 2 thinking is currently applied at the technological (research and development) innovations level tends to mask or generalise the underlying and embedded aspects that are concerned with policy as part of institutional and regulatory innovations. This study illuminates the shifts or changes in regulatory behaviour portrayed by the scientific community as they adapt to different accountabilities demanded by modern biotechnology. This actually calls for further interrogation of knowledge flow and use, integration and relationships concepts in Mode 2 research. This study has enhanced understanding of the important but under-researched distinction between knowledge generated for technological or economic innovations, and knowledge generated for policy innovations in a regulatory context. Both types of knowledge are however important for spurring innovation capacity which depends on productive learning, knowledge flow and use (Hall, 2005) as discussed below.

#### **8.3.1.2 Innovation systems (IS) and policy coalitions**

There were advantages of approaching this study and the associated new knowledge production terrain from an innovation systems standpoint. Innovation systems approach is concerned with how knowledge flows between suppliers and receivers, and how this is translated into useful knowledge through interactions (Clark, 2002). Thus, it pays

particular attention to learning which tends to be taken as given by Mode 2 approach, which is concerned more with the institutional changes that accompany the knowledge production dynamics (Gibbons *et al.*, 1994). The two may therefore be complementary in that they engage with systemic institutional issues. These issues are the ones which were targeted by the current study for potential institutional (governance of biotechnology) reforms. Since IS proposes a holistic view of changes within the dynamic knowledge production terrain (whether technological, policy or regulatory innovations), its concepts can be operationalised in recommending a meaningful scientific/regulatory practice.

Innovation systems literature acknowledges the role of relationships in learning within a system, especially one in a transition. Just like others have noted (cf Hanlin, 2006; Chataway and Hanlin, 2008; Kristjanson *et al.*, 2008), knowledge-flow and learning from knowledge nodes and science-policy boundary organisations are important in strengthening relationships. This study has demonstrated empirically the importance of collective learning and working within a system which supposedly spurs innovative capacity or development in line with other scholars' recommendations (cf Hall, 2005; Johnson, 2007).

Evidence from this study has however challenged the IS concept by suggesting that relationships or coalitions formed in a regulatory context may be counterproductive and may work against the system. This is consistent with policy coalitions literature where learning and consequent relationships building are largely driven by belief systems that may exclude players who hold contradictory beliefs (Sabatier and Weible, 2007). Policy coalitions have exposed the politics inherent in regulatory policy-making as well as the underpinning factors that confound learning and relationships building. The context under which learning occurs in a regulatory context may need to be reconsidered when



researchers are analysing contentious innovation systems in the new life sciences and environmental sciences. In this context, risk perceptions play a major role in influencing the regulatory behaviour of actors and consequently the nature of knowledge that is used in policy processes.

### ***8.3.2 Regulatory policy and practice implications***

As clearly demonstrated in Chapter three, section 3.2 and the entire thesis, this study is grounded in the governance of the new life sciences scholarship. This section is discussed in the context of how this current research has contributed to this scholarship.

#### **8.3.2.1 Contribution to debates on governance in the new life sciences**

This study has revealed the complex scenario under which regulatory actors articulate the governance goal through regulation of biosafety. Beside the technical aspects that confront them, this study has exposed the non technical factors that include social and cultural factors which have to do with the actors' conceptualisation of different aspects of biotechnology and regulation. It therefore exposed the context under which regulatory decision-making processes are articulated by key scientist actors who are supposed to be undertaking various steering roles of the governance agenda. In addition to being driven by different values and interests, cultural practices of these actors tend to shift based on different regulatory and technological contexts. This suggests a need to re-contextualise the scientific community's role as regulatory experts and policy targets in reconciling the conflict between government control and governance that characterises new technologies.

With regards to governance of biotechnologies in Kenya, the practical meaning of governance as moving away from the departmentalised and "do and don't" style of implementing regulations which mimics government control, towards a well-thought-

out integrated approach has not been understood. Governance according to Lyall and Tait (2005:3) “attempts to set parameters of the system within which people and institutions behave so that self regulation achieves the desired outcomes.” This study has re-enforced earlier calls for governance of biotechnology in Kenya and developing countries in general to reconsider practical integration of actors and institutions in decision-making processes if any meaningful gain from biotechnology is to be realised (Harsh, 2005; Clark *et al.*, 2005).

The findings around scientific practice have suggested the need for the scientific community to be aware of the implications of their regulatory actions and decisions. For instance, certain regulatory protocols may be challenging for implementers rather than creating a conducive environment for learning and potential reflexivity. The latter is inclined towards governance since it creates room for iterative adaptation and continued learning (Stoker, 1998, cited in Lyall and Tait, 2005:5). Further, the scientific community within the different arenas and knowledge nodes they engage with needs to develop the capacity to address the different multi-layered challenges in regulatory decision-making processes. This is not easy and comes with not only the re-organisation of institutional set-ups to accommodate more participative decision-making processes (as the governance approach seems to suggest), but also with change of attitudes by the individual social actors.

The normative grouping of the scientific community as one homogeneous group has been challenged by this empirical study. It is emerging that different scientists exhibit different behavioural practices based on different contexts. Some practices for example reflect cultures of groups they find themselves in at different points of their careers. Strategies will need to be designed to incorporate the heterogeneity of the scientists in decision-making processes in order to improve the social desirability of the policy outcomes. This is another way of overcoming the challenges embedded in the legitimate

evidence-based decision making without undermining the role of evidence in the entire process and the rightful role of stakeholders (Tait and Lyall, 2005).

One aspect taken for granted in debates on governance in the new life sciences is the key role scientists play as knowledge drivers. This role is articulated vividly by scholars in sociology of science (cf Jasanoff and Martello, 2004). This strand of scholarship illuminates knowledge as a core output of scientists' interaction with innovations and regulatory processes. The role of knowledge needs to complement debates around the new modes of governance in biosciences that would lead to meaningful economic development (Smith, 2009b). This points towards the importance of rethinking knowledge management in the context of biosafety regulation in order to attain social desirability of the resultant policies. Knowledge management is a responsibility of individual social actors as knowledge users or producers. By operationalising a framework that married the innovation perspective and the knowledge perspective, this thesis has shown how governance of the new life sciences serves as a perfect context in which the two strands of literature conceptually augment each other.

#### **8.3.2.2 Implementation of regulations**

Kenya has been hailed as being a good example in the demonstration of how regulations and innovation can co-evolve while informing each other at each stage. However, analysis of experiences of the scientific community in the implementation of regulations exposes various social and technical challenges that may work against such a model. This empirical evidence seems to support a claim by Haas (2004) that it may be disadvantageous to develop policies simultaneously alongside technological development. This may be linked to the ensuing practice. For instance, evidence from this study suggests that scientific disciplines, professional spaces and knowledge groups in which the “seemingly homogeneous group” of biological scientists belong, instil

cultural values that are consequently reflected in the ensuing scientific and regulatory practices. This has implications on how these actors perceive policy and eventually how they practice policy. This heterogeneity and the potential cultural bias should be considered by policy makers when they engage scientists for policy-making and when making policies that concern them (as implementers and social actors).

### **8.3.2.3 Regulations and the broader innovation goal**

Biotechnology as a tool for innovation in developing countries has been emphasized (Juma and Serageldin, 2007; FAO, 2004). Efforts to achieve the Millennium Development Goals (MDGs) have targeted new innovations like biotechnology (Juma and Lee, 2005). However, as evidence from this thesis points out, endeavours to achieve this may be hampered by contextual factors related to cultural shifts discussed above, that may need to be addressed. This notwithstanding, successful deployment of biotechnology for improved agricultural production is believed to be reliant on effective and conducive regulatory instruments (Bananuka, 2007; RoK, 2006a). This being the case, theoretical science-policy boundary work need reconsideration in order to gain better understanding of the impact of scientific and social factors in policy-making and how this can be brought to bear on socially desirable and pro-innovation policies. This study suggests that a balanced model that looks at the needs of the scientist actors on the one hand, and those of the non-scientific players on the other needs to be developed in the African context. This balance would deal with the complexities discussed head on in order to confront the food security challenge productively.

In Kenya, the legal infrastructure that currently exists (Biotechnology Policy and Biosafety Act) opens up new opportunities for GE technology towards playing a role in attainment of recommendations of the MDGs (RoK, 2005b). This may be viewed as a logical investment in agricultural innovation considering that the available arable land is

hampered by increasing human population, decreasing agricultural production per unit area due to erratic weather and reduced usage of farm inputs as well as diseases and pests attack (RoK, 2005a, 2005b). However there is a real challenge ahead that entails implementation of the Biosafety Act, testing of legitimacy of scientific knowledge, testing of safety and usefulness of scientific products by farmers and testing of the regulatory systems. Already the interviewees were sceptical about the unpreparedness and inadequate capacity on the part of the government systems and public to enforce the Biosafety Act. How then can these implementation problems be addressed to safeguard against possible stalemate and rejection of GMOs by users which can be a big blow to the government and the scientific community?

To address the regulatory challenges reported in the study, different experiences from all actors can be harnessed to improve the regulatory regime at the same time spur economic development (see section 8.3.3 below). Chataway *et al.* (2006) propose an integrated approach to policy and governance that would embrace learnt experiences. This approach “allows for an understanding of the impact of regulation that is more nuanced and resource based” leading to profitable and socially acceptable regulatory and innovation policies (*Ibid*,:180-181).

The following theoretical insights and practical lessons offer some innovative thinking recommendations on how this challenging task ahead may be re-conceptualised.

#### **i. Towards effective learning and use of knowledge**

This study has revealed the important role of knowledge in regulatory policy-making. The problem in Kenya is that the source of knowledge seems to be one-sided, in that it largely comes from scientific experts (who are mainly scientists and connected to government). This one-sided practice has implications.

In a complex science policy terrain with multiple factors working for or against innovation and regulatory processes, the following question posed by Haas, (1992:1) is very valid. Can policy makers or scientists themselves *“identify national interests and behave independently of pressures of social groups they nominally represent?”* He argues that, actors can learn new patterns of reasoning informed by a wider stakeholder needs and interests. The general argument advanced here is that scientists can genuinely play their part to influence positive change in policy-making through appropriate use of knowledge and information (Haas, 1992:3). The scientific community has a major role to play in this because they understand the complexities and uncertainties associated with biotechnology better than the non-scientists and policy makers (Bradshaw and Borchers, 2000). From an institutional point of view, the formulation and subsequent review of regulatory policies should be open and transparent as suggested by some interviewees. In addition, inclusion of a wide range of expertise that encompasses non-technical professionals is a positive way to democratise the process (Nowotny, 2003).

This study further suggests a change of attitude of actors towards a socially responsible process. The scientific community and policy makers, and those groups that claim to represent the farmers and public must be honest with no hidden agenda (Ammann and Ammann, 2004) while at the same time being reflexive towards integration of other diverse views in policy-making process (Lyll *et al.*, 2009c:261).

## **ii. Towards a productive public engagement**

Scientists admitted that the introduction of biotechnology and subsequent policy process was “hyped” and only realised the negative implications of this approach during the formulation of the biosafety bill. However, there was a positive re-conceptualisation of

the role of the public which saw the birth and launch of the BioWARE initiative.<sup>208</sup> It is this kind of public awareness and an all-stakeholders dialogue that must lie at the centre of an effective regulatory process, which encourages the interrogation of scientific claims, and ensures a more inclusive form of debate on issues pertaining to GE technology and its potential to spur economical growth in the Kenyan agricultural sector. This must be done on the premise that decisions on biotechnology regulation cannot be done on the basis of sound science alone (Newell, 2002). This points towards a responsive and accountable process hence a wider scope as well as a new agenda for policy and practice in the post-Biosafety Act approval phase (Lyll, *et al.*, 2009b).

There is now a legal framework where all players have been empowered (RoK, 2009). It has mechanisms for public participation and education. The scientists can undertake research while the public can demand proper public education. This platform can be used constructively in engagement of all stakeholders in the GE products implementation phase.

Although genuine public participation is important as a way to dialogue with public regarding science, care should be taken to avoid “quantity of views” at the expense of “quality and content” of what is brought to the table for discussion (Durodie, 2003). Care also should be taken to ensure genuine representation. As others have noted (cf Harsh, 2005), this research project reported increased proliferation of institutions (NGOs, scientific, civil society) towards the last one decade purportedly representing the interests of farmers and public in biotechnology governance. Durodie (2003: 87) notes that these “self appointed voices of authority” tend to confuse the public dialogue

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<sup>208</sup> During the BioWARE launch, the chief executive of KENFAP (an association bringing farmers together) and the Director of Agriculture appealed for a radical and strategic attitude change in order to reverse the purportedly scientific and industry led innovation approach, towards a process that recognises the need to take the users of the technology along (recorded speeches during BioWARE launch on Sep 2008 in Nairobi and analysis of the BioWARE strategy, RoK, 2008b).

and it becomes difficult to know “who to believe.” Harsh (2009) has empirically shown that it is possible for NGOs to misrepresent the same people they purport to represent.

### **8.3.3 Lessons for practice**

This section looks at insights that this study can draw from Kenya’s one and half decades of biotechnology and regulatory regime co-evolution in terms of practice. Three distinct aspects are key in putting the lessons discussed here into context:

***Dynamism:*** Biotechnology innovation is advancing at an unprecedented pace, perhaps faster than the capacities of actors and institutions to adjust in order to accommodate the requisite changes needed to foster innovation and responsive engagement of stakeholders, including regulation (Tait *et al.*, 2006:379). This has called for new styles of governance as Lyall and Tait (2005) contend.

***Multifaceted:*** The twin processes (biotech innovation and regulatory process) involve many actors with each process being multifaceted. The policy and regulatory process and the accompanying practice in life sciences in particular is perceived to be problematic because of the different policy cultures that different actors exhibit at the global and regional levels (Murphy and Chataway, 2005) and at national levels including developing countries (Lyall *et al.*, 2009a).

***Complexities related to cultural shifts and practice:*** The entire biotechnology and regulation revolution involves complex economic and institutional dynamics exhibiting characteristics within a Mode 1 - Mode 2 knowledge production continuum. Actors oscillate within this continuum with different technological and regulatory impacts. The behavioural shifts tend to be prominent during regulations implementation with different cultural identities impacting different demands and contributions that have implications for the resultant regulatory instruments. It is very important to note that these cultural dynamics are complex in nature, value-laden, interest driven, with varying



expectations from peers and relationships. These shifts are sometimes encouraged by the inadequate and specialised biotechnology-biosafety knowledge capacities needed to move biosafety policy process forward. This may not be construed to be a bad thing because within a dynamic and functional system operating from an innovation system perspective, this may promote cumulative knowledge and learning. However, how learning and knowledge are managed is important for practice.

A number of lessons can be drawn in relation to knowledge use and policy-making as explored below.

#### **8.3.3.1 Harnessing the positive aspects**

The positive aspects of these cultural dynamics need to be harnessed. We cannot rule out the important learning that has taken place in the last one and half decades both at the institutional and individual levels, much of which is tacit. The government has to look for ways of using this accumulated knowledge. One way it can do this is to compile a list of experts who have been involved, and perhaps include and consider them as official experts under the provisions of the Biosafety Clearing House (BCH).<sup>209</sup> They would then be called upon from time to time in capacity building efforts at various fora or public education campaigns. In addition to sensitising people about specific technical subjects, they would also be requested to talk about their experiences in biosafety regulatory process, providing a platform for meaningful deliberations that can advance pro-poor and pro-innovation agenda.

#### **8.3.3.2 Dealing with the negative aspects**

It is possible that the cultural dynamics discussed above may have a negative impact on final regulations and implementation. For instance, the scientific community's active

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<sup>209</sup> BCH is a mechanism set up by the Cartagena Protocol on Biosafety (2000) to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol ([www.bch.cbd.int](http://www.bch.cbd.int)).

participation in the regulatory process may have resulted into more of technical and scientific knowledge informing the policy deliberations. This may have ignored some other relevant knowledge which may enhance compliance with biosafety regulations.<sup>210</sup>

These possible negative aspects cannot be ignored and have to be factored into future regulatory decision-making processes. How can this be done?

- The government has a major role to play by adopting a governance approach through weighing and analysing the types of knowledge that inform the process. The objective would be to ensure that socially desirable knowledge informs the final policy outcome (Nowotny *et al.*, 2001).
- The government needs to build and sustain technical capacities thereby have a wide pool of experts in which to draw expertise from. It should also spread its wings to other academic, non academic and research institutions to solicit expertise not only for regulatory instruments, but also for overall risk assessment and environmental safety reviews.

### 8.3.3.3 Reconceptualising policies formulation process

In addition to the above lessons, the significant cultural shifts demonstrated empirically in the Kenyan case that accompany the biotechnology and biosafety revolution lead to a compelling urge to reconsider how policy and regulatory formulation processes are conceptualised and articulated. Regulatory practice, if it is to achieve greater effect in reconciling the governance agenda of modern biotechnology on the one hand, and role

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<sup>210</sup> For instance local environment under which "refugia" may work if *Bt* maize is introduced into farmers' fields. "Refugia" refers to fodders or cereal crops that foster the survival and reproduction of *Bt*-susceptible borers, hence ensuring sustainability of the insect resistance trait of the transformed maize. For this to happen, "the refugia species have to fit in with the farmers' cropping systems." (Margaret Mulaa, KARI scientist quoted in GENET a European NGO on GE) accessed on 12/09/09 at [www.genec.ch/genet/2006/Jan](http://www.genec.ch/genet/2006/Jan). The farmers have better knowledge of their farming systems that may work better to ensure terms and conditions of GMOs release are adhered to. This is good for both researchers and the government who want to see technologies succeed, are adopted and sustained. It is also good for regulators who want to see that regulations are complied with.

of actors in providing evidence-based input into the process; it must factor into the process this cultural shift.

This is not to denounce the economic and institutional changes in which this shift is embodied, but rather to suggest that this becomes an additional consideration in policy processes. Since this cultural shift is exhibited by actors spread out in different institutions (academic, policy, NGOs, public), effective policy and regulatory processes must first acknowledge its potential to influence policy directions. Consequently, strategies should be devised that encourage a reflexive and responsive behaviour (Lyll, *et al.*, 2009c: 261). This may enrich how policies are implemented considering that cultural practices in life sciences are linked to values and interests (Laurie *et al.*, 2009). This current research has just provided a pointer towards this direction.

#### **8.4 Suggestions for further research**

To generate productive policy and innovative strategies, there is need for more empirical research to allow further assessment of local dimensions of regulations implementation. Involving a wider group of actors beyond the scientific community and outside the biosafety arena would add value to this process. Exploring the following strategies may enhance the attainment of these goals.

- Empirically this study has shown that the institutionalisation of the biotechnology system in Kenya involves both institutional and shifts in cultural practice from Mode 1 to Mode 2. The latter is linked to the behavioural practices of the scientific community as important actors in this process. It is however unclear how particular values embedded in respective cultural spaces are upheld as individuals move from one professional career to another or as players oscillate within Mode 1 - Mode 2 continuum. It would be imperative therefore to

explore to what extent cultural bias related to different disciplines and professions in which scientific community belong to impact policy change.

- The heterogeneity of the scientific community may be advantageous in many aspects as the current study suggests. However, research focusing on a significant number of biological scientists from the seemingly non-practising and non-policy institutes or civil society who may have contrasting views may be crucial. This is definitely a target group that would yield considerable useful and comparative data pertaining to scientists' perceptions and practice related to controversial technologies in life sciences.
- This thesis employed an analytical framework that encompassed a mix of concepts drawn from sociology of science and innovation systems literature. It would be important to test this framework in different contexts (for instance in another country) to enhance generalisation of the results.

## **8.5 Research limitations**

Access to some interviewees who seemed to have opposing views was constrained by the prevailing suspicion amongst proponents and opponents prompted by the biosafety bill controversies. For instance, I managed to interview a molecular scientist from civil society (presumably an opponent) but he refused to sign the consent form and also demanded that I switch off the audio recorder at some point. He feared that his views may be misinterpreted by fellow scientists (proponents).

The familiar research terrain discussed exhaustively in Chapter four may have had some limitations in that participants may have unintentionally withheld some information, assuming that I understood the context as they did. These limitations and other possible negative validity issues were checked through triangulation as detailed in Chapter four.

## 8.6 Chapter conclusion

This thesis has highlighted that investigating scientific practice in an institutional setup provides crucial insights that can improve the productivity of the broader biotechnology innovation system. Implementation of regulations as a subcomponent of the broader biotechnology innovation system that has been undergoing revolution for about one and half decades presented a dynamic “sub process” where both institutional and cultural factors interplay to influence policy (regulatory policy). Analysis of this process suggests that both institutional and cultural shifts occur, perhaps in the same magnitude to direct the regulatory process. The latter is associated with shifts in scientific and regulatory practice as the scientific community adapt to the new working environment characteristic of biotechnology research.

The study has also made explicit the underpinning factors that characterise the process of learning and relationships/coalitions building in the formulation of regulatory policies. These factors range between belief systems, interests and values held by the stakeholders who include not only the scientific community, but also the non-scientific fraternity labelled as “opponents” in this study. The tensions that emanate in the process expose the political nature of the wider biotechnology innovation system and its governance.

Overall there have been incremental and unprecedented efforts to incorporate the regulatory system and related institutions as part of the governance into the broader biotechnology innovation system.<sup>211</sup> This process has not been static for the last one and half decade. This thesis confirms the complexity of establishing “effective” regulatory instruments and that this process is underpinned by many perceptions and practice related factors that only become vivid in an empirical study like this one. Theoretical and policy implications have been explored, exposing strengths and weaknesses in the

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<sup>211</sup> Biotechnology innovation looked from a broad sense would reflect the non linear, complex and iterative interrelationship between the three key components illustrated in Fig. 1 (Chapter one).

Kenyan system. The strengths need to be harnessed and weaknesses looked into, towards a smart and productive regulation.

## **8.7 Epilogue**

Having a flashback, and reflecting on where I began the journey, I can say the entire PhD process has been both challenging but above all, transforming in terms of critical approach to issues. It has been more than an academic journey. Coming from a biological and positivist background, perhaps where critical perspectives may be constrained by many factors like methodological issues, I can confidently say that I am better placed to deal with social and policy related subjects, more generally.

But beside the personal and professional gains, this study set out to investigate perceptions of the scientific community related to regulations and regulatory practice, based on my pre-conceived ideas and perceptions that I had formed prior to the study. I was later to discover that regulatory issues are complex, hampered by many factors that have major implications for policy and practice, and the broader innovation policies. I therefore approached this study with a reflexive mind, coming up with what I believe is significant contribution to knowledge and policy.

More significant is the post-PhD life. I believe all these attributes, skills and challenges will continue to impact positively my contribution to the field of life sciences and biosafety regulation, development studies, and the broader social and development policies.

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# Appendices

## Appendix 1: Categorisation of participants based on interviews & professional profiles

No.	Participant code <sup>212</sup>	Type of organisation	Discipline/ description of professional role	Interview date
<b>GE Practitioners (GP)</b>				
1	RSPu-GP1	Public research institute	Molecular science/plant research scientist	30/01/08
2	RSIn-GP2	International research institute	Plant breeding/plant research scientist	11/12/07
3	RSIn-GP3	International research institute	Molecular science/plant research scientist	17/03/08
4	RSPu-GP4	Public research institute	Insect entomology/plant research scientist	16/11/07
5	RSAc-GP5	Public university	Molecular science/academic & plant research scientist	11/12/07
6	RSPo-GP6	Regional organisation for biotechnology research & development and biosafety capacity building.	Medical bioscience/biosafety & biomedical research scientist	1/03/08
7	RSPu-GP7	Public research institute	Animal (veterinary) science/animal research scientist	11/01/08
8	RSPu-GP8	Public research institute	Agriculture science/junior plant research scientist	18/12/07
9	RSIn-GP9	International intermediary organisation with links to international & public research institutes.	Ecology & environmental science/ plant research scientist	27/11/07
<b>Policy Scientists (PS)</b>				
10	Blp-PS1	Government institute for science and technology	Chemistry & hydrogeology/ biosafety policy	24/01/08
11	ARp-PS2	Ministry of Agriculture	Plant pathology/agricultural & regulatory policy	14/01/08
12	ATp-PS3	Public university	Mycology/academic, technological & biosafety policy	23/11/07
13	PRp-PS4	Regulatory agency	Plant pathology/plant regulatory policy	12/02/08
14	ATBp-PS5	Public university	Biochemistry/ academic, technological & biosafety policy	22/11/07
15	RSIn-PS6	International research institute	Micro-biology/ general health & safety	8/11/07
16	RSPu-PS7	Public research institute	Plant science/technological research & policy	27/11/08
17	RSPu-PS8	Public research institute	Animal science/ technological research & policy	25/01/08
18	ARp-PS9	Regulatory agency	Veterinary Virology/ animal regulatory policy	30/10/07
19	PRp-PS10	Regulatory agency	Plant pathology/plant regulatory and biosafety policy	09/01/08
20	Blp-PS11	Government institute for science and technology	Plant pathology/biosafety policy	16/02/08
21	FSp-PS12	Regulatory agency	Food & nutrition science/food safety policy	02/11/2007
22	Blp-PS13 <sup>213</sup>	Government institute for science and technology	Building economics/biosafety policy	31/10/07
23	ABp-PS14	Ministry of Agriculture	Agricultural science/technological & biosafety policy	18/02/08
24	ENp-PS15	Regulatory agency	Environmental science/environmental	28/03/08

<sup>212</sup> Description of each participant varies based on anonymity requested. Some wanted institutions they work for disguised. For abbreviations, see pages x-xi.

<sup>213</sup> Not a biological scientist but his position as a key government biosafety policy advisor prompted his placement in this category. His statements are analysed from only a policy perspective.

			policy	
25	ARBp-PS16	Public university	Plant breeding/academics, plant research scientist & biosafety policy	14/03/08
<b>Non State Scientists (NSS)</b>				
26	TAR-NSS1	International pro-biotechnology NGO	Biotechnology/technology advocacy & research	4/02/08
27	TAN-NSS2	International pro-biotechnology NGO	Environmental science/ technology advocacy	30/01/08
28	TRTp-NSS3	Local seed traders association	Plant breeding/technological research & trade policy	15/11/07
29	TAN-NSS4	Regional pro-biotechnology NGO	Agriculture science/ technology advocacy	31/10/07
30	EPA-NSS5	Environmental NGO (civil society)	Molecular biology/environmental protection advocacy	24/01/08
31	TAD-NSS6	Pro-biotechnology donor agency	Molecular biology/ technology advocacy	1/02/08
<b>Non Biologist Scientists &amp; Non Scientists (NS)</b>				
32	NGOf-NS1	NGO (local organic farmers)	Horticulture/environmental protection & farmers' rights advocacy	21/11/07
33	NGOf-NS2	NGO (local farmers & producers)	Social science/ farmers' rights advocacy	5/11/07
34	NGOcs-NS3	Environmental NGO (civil society)	Agriculture economics/civil society's rights advocacy	24/01/08
35	NGOco-NS4	NGO (consumers)	Statistics/consumers' rights advocacy	21/01/08
36	NGOco-NS5	NGO (consumers)	Food nutrition/ consumers rights advocacy	21/01/08
37	JO-NS6	Local daily newspaper	Journalism/ science editor	1/04/08
38	JO-NS7	Local daily newspaper	Journalism/ science editor	20/03/08
39	LABp-NS8	Attorney General's chambers	Law & environmental science/ parliamentary counsel on biosafety policy	23/01/08
40	LAEp-NS9	Regulatory agency	Law/environmental policy	28/03/08
41	TAI-NS10	Biotechnology industry	Food science/technology advocacy	21/01/08
42	TAD-NS11	Pro-biotechnology donor agency	Development policy/ technology advocacy	27/03/08

Source: Secondary and interview data



Appendix 2: Interview sample guide

Policy group-(regulators, senior government officers, Legal officers, selected non researchers who are NBC members)

Name of Interviewee.....

Date of interview.....Time.....Place.....

PART 1: General information

a) Occupation: (To tick more than one if necessary)

Occupation	(Tick)	Institution Name	Status/Nature of interviewee*
Biotechnology researcher			
Policy advisor			
Field trials/GM regulator			
Government official: Senior			
Middle			
Junior			
Private sector/Industry official etc			
NGO staff – International, regional or multilateral			
-Donor-capacity building			
-Donor - funding			
Media staff			
Other (specify)			

\*Nature/ status of the scientist/interviewee (to choose from this table)

Tick appropriate
Practising/bench scientists
Lab technician/ greenhouse technician/field trial manager
Administrative scientist (Project coordinator, Principle investigator)
Institutional Biosafety Committee (IBC) member
National Biosafety Committee (NBC) member
Pro-GMOs activist
Anti-GMOs activist
Any other (Specify)

b) Project (Field Trial).....

c) Discipline/Profession: (tick more than one if necessary)

Discipline	Tick	Institution	Role
Molecular biologist			
Entomologist/Nematologist			
Plant pathologist			
Plant breeder			
Tissue culture			

Bio-informatics			
Biochemists			
Botanists			
Social scientists -Sociologist -Social economist -Extension -Other			
Lab technologists/Technician			
Student			
Other (specify)			

**d) Partners (list all for each project)**

Partner	Role

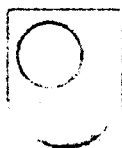
**General Observations:** *(Detail minor happenings and interview setting).*

**PART 2: Questions guide on biosafety regulations and implementation**

1. What is the view or position of your institution/ministry on GMO's?
2. What is your personal view about GM research and development? What is your view about the field trials? Why do you hold this view?
3. What do you think of the biosafety regulations that are being used in regulation of GM field trials?
  - a) Which one in particular do you think are useful? Do you think they provide adequate guidance in the conduct of field trials in Kenya?
  - b) Do you think they are impacting upon GM research work in any way? If yes, do you think this is compromising safety?
  - c) Did your institute/ministry participate in any way in the drafting process? If yes, which role did it play? If no, why did it not participate? In your view, should it have been involved? Why?
  - d) Were you involved in any way in the drafting process of any of the legislation? If yes, in which capacity- as a scientist, as an individual or representative of your institution? How were you involved? Any comments on the drafting process?
  - e) The research scientists involved in this process, which role do you think they played? Do you think this has an effect on GM research work? What about the final regulatory instruments?
4. The essence of RA as well as accompanying regulations and related policies that guide in RA is to minimise risk to the environment.
  - a) What does risk mean to you?
  - b) What do you think are biosafety risks in a field trial-CFT? (Risk to biodiversity, cross pollination etc?)
  - c) How should judgement on risk be made? How should risk be quantified?

- d) How should RA be conducted i) during the review of a CFT application ii) during the trial – in the field? Do you think the Regulations and Guidelines that exist provide adequate guidance for RA?
  - e) Are measures being employed to address biosafety risk in the field trials (CFTs) adequate in your view? If no, why?
- 5. What is the role of the field trials in generating information on biosafety risk?
  - a) How is this data used by policy makers? Do you think it is useful? Why?
  - b) How can the process of generating, compiling and reporting RA information be made better for enhanced decision making by decision makers at IBC/NBC?
  - c) What role do you think the scientists/researchers who participate in RA process play?
- 6. Having talked about various issues on biosafety regulations, in your view, what are the factors affecting the regulations implementation in relation to GM research work?
  - a) Among these factors, which one do you consider to be the most important? Why?
- 7. Have you participated in monitoring and inspection of the field trials?
  - a) What concerns do you address during the M & I/what do you look for in particular? What are your experiences? Are the trials being conducted according to the regulations? If no, why?
  - b) How can this process (M &I) be made better?
  - c) What will be required to improve it the way you have described?
- 8. Do you think the views of your institute/ministry are represented in decisions pertaining to GM field trials? If yes, how? If no, why do you think so? Do you think it should be represented? Why? (*Asked if necessary*)
- 9. Some people believe that international donors/biotechnology industry in Kenya have had too much influence on biosafety policies in Kenya. Do you hold the same view?
- 10. Some others believe that our research scientists have been compromised by the international donors/biotechnology industry. Do you hold the same view as well?
- 11. Some people believe that scientists have influenced the biosafety regulations development process (e.g. the biosafety bill) in favour of GM work. What is your comment on this?

## Appendix 3: Letters of cooperation and consent



The Open University

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Development Policy and Practice  
The Open University  
Walton Hall  
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MK7 6AA  
United Kingdom  
Tel +44 (0) 1908 653 651  
Fax +44 (0) 1908 654 825  
dpp@open.ac.uk  
www.open.ac.uk

To whom it may Concern:

Ref: Y0231953

**SUBJECT: ANN NJOKI KINGIRI**

---

This is to confirm that Ann Njoki Kingiri is registered as a PhD research student, at Open University in Milton Keynes. UK.

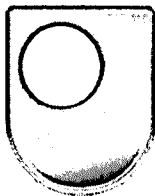
As part of her doctoral research, she is conducting a study on "Implementation of regulations governing risk in modern crop biotechnology in Kenya".

I should be grateful for any assistance accorded to Ms Ann Kingiri to further her research work.

Yours faithfully,

Professor Hazel Johnson  
Head of Department  
Development Policy and Practice  
Faculty of Technology  
Open University  
Milton Keynes, UK

**Development Policy and Practice**  
Technology Faculty  
The Open University  
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## SUBJECT: CONSENT FORM

I am a research student currently undertaking doctorate studies at Open University, in UK. My research intends to examine the different stakeholders' perspectives on biosafety regulations and implementation in Kenya and consequently try to situate those perspectives in a systemic understanding of biotechnology innovation in Kenya.

As part of my research work, I am asking for your consent to conduct an interview with you and with your permission digitally record our discussion. This is mainly to help me remember key aspects of our discussion. If you tell me of any aspect of our discussion that you wish to remain private or confidential, I will not divulge it to anybody. If you wish that I destroy any of the data that you provide, I will do so. If you decide to withdraw from participating in the interview, you may do so at any point.

In reporting this research, I may describe our discussion and use short quotations from your words without mentioning your name and without including any details that might identify you. Otherwise in reporting the research, if I require to use any quotation that might identify you, or use any excerpt from the audio recorder, I will honour your decision as provided below.

My notes of our discussion and the full audio or software records will be held securely and accessed only by myself.

Should you wish to discuss any aspect of your participation in this research, you can contact my supervisors:

Professor Joanna Chataway  
Innogen Research Centre, Open University  
Walton Hall, Milton Keynes  
MK7 6AA, UK  
Tel. +44 (0) 1908 655119  
E-mail: [J.C.Chataway@open.ac.uk](mailto:J.C.Chataway@open.ac.uk)

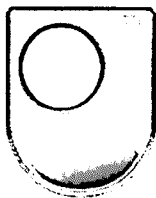
Dr. Seife Ayele  
Technology Faculty, Open University  
Milton Keynes MK7 6AA, UK  
Tel. +44 (0)1908 655534  
E-mail: [s.ayele@open.ac.uk](mailto:s.ayele@open.ac.uk)

Ann Njoki King'iri... *Ann Njoki King'iri*

I agree to be recorded and interviewed as described above

I agree to be quoted


Signed.....Date.....



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www.open.ac.uk

Prof/Dr/Mr/Ms/Mrs.....

Date: .....

**SUBJECT: INVITATION/INFORMATION LETTER**

I am a doctoral research student, at Open University in Milton Keynes, UK. As part of my research, I am conducting a study on **“Implementation of regulations governing risk in modern crop biotechnology in Kenya”**. This study focuses on scientists’ perspectives on biosafety regulations and implementation with a hope of identifying the regulatory challenges and opportunities that exist as they carry out their GM research work. Consequently it is hoped that their views and experiences can be harnessed to improve regulatory instruments and processes in Kenya.

Considering your role in crop biotechnology research and your experience in regulation, I would be very grateful if you would kindly spare your time for an interview at a time convenient for you.

I would like to state that this study is conducted independently and is not conducted on behalf of any organisation or institution. It is sponsored by Open University, Technology Faculty department which is hosting me currently for the period of the study. All the information you provide during the interview will be treated as strictly confidential. If you wish the data provided to be destroyed, that will be done. In reporting this research, I will do it in such a way that you or your institution will not be identified. If you wish to be quoted in any way, you may give an approval as provided in the consent form.

I am fully aware that the interview will require your precious time, but this is the only way I can interpret your worldview as narrated by you; based on your experience. I thank you for your cooperation and hope to hear from you.

Yours sincerely,

Ann Njoki King'iri

## Appendix 4: Connecting codes to themes

*Perception of regulations:* Label from 1<sup>st</sup> level coding  
*Participants:* Organizational category (column 1)  
*Perceptions:* Labels from 2<sup>nd</sup> level coding (column 2)  
*Themes:* (column 3)

Participants	Perceptions (from 2 <sup>nd</sup> level coding)	Themes
GE practitioners	<ul style="list-style-type: none"> <li>-A law need to be supported by regulations and guidelines for operationalisation.</li> <li>-It is only during implementation of the regulations that weaknesses can be detected &amp; addressed accordingly through appropriate review; Review should consider users' experiences; development needs to be done with users in mind.</li> <li>-Regulations providing guidance in trials management but have aspects which are not relevant &amp; need to be reviewed; building trust and confidence in GE activities; bench mark for RA; useful for RA, confinement, trials monitoring &amp; proper management; standardizing trials operations.</li> <li>-Regulations need to distinguish GE developmental stages since risk issues are different.</li> <li>-Regulations overly cautious and are not user friendly and create public suspicion; This is justified by perception that GE is new technology but this can be addressed through public education.</li> <li>-Regulations give a risky expression of GE technology.</li> <li>-The early regulations were formulated to test &amp; move GE technology forward a move that is appreciated by researchers.</li> </ul>	Narrow view- regulations for science advancement
Policy scientists	<ul style="list-style-type: none"> <li>-Regulations development perceived to be continuous process to accommodate international agreements.</li> <li>-Existing regulations formulated with insights from other statutes but experiences in implementation informs the need for review.</li> <li>-The grey areas are left for inclusion in the regulations that are to be developed.</li> <li>-Regulations should consider technology developers &amp; users.</li> <li>-Precautionary approach adopted to assess &amp; manage risks considering that capacity for risk analysis was low. It was also to address uncertainty; The risk regulation approach adopted is negative and not facilitative; Precautionary approach is good but reasonable caution needed to permit research.</li> <li>-Regulations formulation was to move science forward hence it was science being regulated &amp; not products; Initial regulations to address confinement hence capacity perceived to be adequate.</li> <li>-RA pertaining to non-targets &amp; safety based on local information has not been satisfactory.</li> <li>-Regulations have created confidence thus enhancing biotechnology research within institutions; provide for learning and ownership of the process; enhancing institutional operations; facilitating science by asking precautionary questions; addressing science &amp; confinement not product or food safety; promoting confidence in activities being conducted.</li> <li>-Whether regulations are cautious or promotional depends on whether one is pro biotechnology or opponent.</li> <li>-Regulations should be promotional for R &amp; D to allow investigation &amp; clarify issues.</li> </ul>	Broader view- regulations for development and safety
NGO scientists	<ul style="list-style-type: none"> <li>-Regulations (1998) borrowed heavily from other regulations.</li> <li>-Law misunderstood to be an end whereas regulations are to address safety issues.</li> <li>-Regulations formulation process not well understood.</li> <li>-Social issues if put in regulations would hinder science; regulations formulation process in Africa should be free from Western politics &amp; take cognisance of Africa unique needs.</li> </ul>	Broader view but regulations for science products

	<p>-The regulations should have an eye on science (production), importation and exportation of GE products.</p> <p>-Regulations should ensure science that is sensitive to cultural and societal issues.</p> <p>-Regulations of 1998 considered confinement to move GE technology forward &amp; had regulatory oversights due to inadequate containment facilities.</p>	
Non scientists	<p>-Regulations being developed with wide range of users in mind, an approach different from the 1998 regulations which were basically science driven.</p> <p>-Technology advancement is perceived to be unstoppable &amp; regulations needed therefore to regulate GM products.</p> <p>-Regulations restricting public due to their confinement nature.</p> <p>-Purpose of regulations can be perceived differently by scientists as either facilitating or hindering research.</p> <p>-Regulations (1998) were developed to move science but cannot withstand legal challenge.</p> <p>-Regulations &amp; RA process not clear since RA per se is not conducted locally.</p>	Broad view hence regulations are overly permissive and promotional
Non scientists (industry/donor)	<p>-The process of regulatory policy formulation is not taken seriously in Africa hence slow GE adoption process.</p> <p>-Regulations overly cautious due to public perception of GE as new science, however this creates satisfaction that the technology is being handled responsibly.</p> <p>-Regulations should have provision for review with technology advancement.</p>	Broader view- regulations for science products hence restrictive



<b>Institutional Actor (see abbreviations on pages ix-x)</b>	<b>Description</b>	<b>Role related to GE activities</b>	<b>Social actor link</b>
KARI	Public research	GE research in partnership with the industry and donors.	RSPu-GP1, RSPu-GP4, RSPu-GP7, RSPu-GP8, RSPu-PS8, RSPu-PS7
KEPHIS	Phytosanitary regulatory agency	Monitoring and inspection (M & I) of plant related GE research.	PRp-PS10, PRp-PS4
NEMA	Environmental regulatory agency	Environmental Impact Assessment (EIA) and M & I of GE products after deliberate release.	ENp-PS15, LAEp-NS9
DVS	Zoo-sanitary regulatory agency	M & I of veterinary related GE research including animal vaccines.	ARp-PS9
KEBS	Standards regulatory agency	Standards development including labelling of GE products.	FSp-PS12
Public Health	Sanitary regulatory agency	M & I of health related aspects of GE products.	-
Universities	Public academic institutes	Training on GE technology & conducting GE research under confinement.	ATBp-PS5, ATp-PS3, RSAC-GP5, ARBp-PS16
NCST	Government body	Issues research permits. Mandated to implement the RoK (1998), coordinating regulatory process including policies formulation.	Blp-PS1, Blp-PS13, Blp-PS11
NACBAA	Adhoc advisory committee	Advice government on biotechnology science in early 1990's.	Blp-PS11, TAN-NS4
MOA	Government ministry linked to farmers	Extension services.	ABp-PS14, ARp-PS2
NBC	Committee bringing stakeholders together under coordination of NCST.	Deliberate on biosafety matters. Members of taskforces drafting the regulatory instruments were drawn from this committee. Has 5 NGOs representatives. <sup>215</sup>	Many interviewees are NBC or IBC members
ABSF	Regional pro-biotechnology NGO, founded in 2000.	Public awareness on biotechnology and perceived to be promoting biotechnology.	TAN-NS4, ATBp-PS5, RSIn-GP9
KEGCO	Coalition bringing previously seven NGOs actors together, established in 2004.	Lobbying for public involvement in deployment of GMOs.	NGOf-NS1, NGOf-NS2, NGOf-NS3, NGOf-NS4, NGOf-NS5
KBioC	Previously KEGCO but with more NGOs actors. Became active in 2007.	Lobbying for public involvement in deployment of GMOs and against the enactment of the biosafety bill.	NGOf-NS1, NGOf-NS2, NGOf-NS3, NGOf-NS4, NGOf-NS5
CIN	Local consumer organisation and appointed public representative at NBC.	Partners with other NGOs to lobby for consumers views particularly food safety issues and labelling of foods derived from GM.	NGOco-NS4, NGOco-NS5
KENFAP	Farmers' organisation and appointed public representative at NBC.	Partners with other NGOs to lobby for farmers' views on GMOs matters.	NGOf-NS2

<sup>214</sup> *Note:* There are more actors in the biotechnology arena but those analysed in this table are linked to interviewees in various ways. Most of these actors have collaboratively been sources of knowledge or dissemination nodes. Through them, biotechnology and biopolicy capacity has been built. Others capacity building efforts include Cochran fellowships programme funded by USAID and targeting policy makers & regulators; FAO biosafety programme coordinated through KEPHIS; Danforth Plant Science Center in USA, partnering with regulators and research scientists; specific training funded by pro-biotechnology NGOs like ABSF, A-Harvest International; and the Biosafe Train project which is Danish funded project that continues to train students at MSc and PhD level in risk assessment (see [www.biosafetrain.dk/Home/About.htm](http://www.biosafetrain.dk/Home/About.htm)).

<sup>215</sup> CIN; ABSF; Kenya National Farmers Union (KNFU) now known as KENFAP; Seed Traders Association of Kenya (STAK) and BTA. (See also Appendix 8).

Action-Aid	International NGO	Funds anti-GMOs activities especially the anti-biosafety bill process through its partners like KEGCO and KBioC.	EPA-NSS5, NGOs-NS3
ABSP, USAID, PBS, IFPRI	International organisations affiliated to USA.	Support for GE research mainly through USAID (e.g. transgenic sweet potato and rinderpest vaccine through the ABSP programme). Support for establishment of a biosafety regime through PBS and science communication through IFPRI & ISAAA.	TAD-NS11, TAD-NSS6, TAN-NSS2
CIMMYT	International CGIAR	In partnership with KARI and other partners is behind the IRMA <i>Bt</i> maize project.	RSIn-GP2
Monsanto	Biotechnology industry	In partnership with KARI and other partners is behind the <i>Bt</i> cotton project and is partner in the IRMA <i>Bt</i> maize project.	TAI-NS10
KBC (Kenya Biosafety Coalition)	Strategic adhoc coalition comprising of scientists in biotechnology and policy arena.	Established in 2007 to lobby for the enactment of the biosafety bill.	Most interviewees confirmed that they were members.
ISAAA-Afri Center	International organisation	Public awareness through provision of biotechnology information. Collaborates with research institutions as partner in biotechnology projects. Coordinated biosafety bill lobbying activities of the KBC. Involved in science communication. It is a co-founder and convener of the OFAB forums.	TAN-NSS2
DGIS	International donor organisation (Dutch).	Supporting biotechnology advancement in early 1990's and drafting of first regulations in 1998. These activities were advanced through the local NGO, KABP.	TAN-NSS4
BTA (Previously KABP)	A pro-biotechnology organisation	Initiated and supported the formulation of the first Regulations and Guidelines of 1998 through DGIS funding. It opened up opportunities for funding policy-related issues.	TAN-NSS4
Africa Harvest Biotechnology International (A-Harvest)	International pro-biotechnology NGO	Promotion of biotechnology. It is behind the fortified sorghum being targeted for introduction in Africa. Together with other KBC partners it supported outreach and sensitization of policy makers and parliamentarians on biosafety bill.	TAR-NSS1
AATF	International initiative and pro-biotechnology organisation.	Supports the acquisition of new technologies by farmers through negotiating for intellectual properties rights owned by multinationals or other patent owners. It partners with other pro-biotechnology organisations to lobby for facilitative regulatory instruments that can promote biotechnology. It is a co-founder and convener of the OFAB forums.	RSIn-GP9
OFAB	Forum for biotechnology	A platform that brings together stakeholders in biotechnology and enables interactions between scientists, journalists, the civil society, industrialists, lawmakers and policy makers.	Most interviewees are members.
BECA	Regional initiative under NEPAD	Biotechnology research & development, biosafety capacity building within Africa.	RSPo-GP6
BioWARE	Public awareness initiative spearheaded by scientists in both public & private sector, farmers & government.	Initiated through the Ministry of Agriculture to sensitize farmers on biotechnology matters.	Many interviewees involved in this initiative.
Nation media group, Standard newspaper, The People Daily, Kenya times, Science Reports magazine	Media	An arena exposing controversies as different actors advanced diverse viewpoints related to biotechnology and biosafety policies.	JO-NS6, JO-NS7

Source: Interviews and secondary data.

## Appendix 6: Phases of Kenyan biotechnology regulatory process and implementation

Phase	Activities	Proactive actors	Output/Comment
1 1990-1998	<ul style="list-style-type: none"> <li>Transformation of sweet potato in USA.</li> <li>Regional conference on safety in biotechnology in 1993 exposed early scientists to biosafety regulation. Task force formed after this conference to draft regulations 1996-1998.</li> <li>Drafting of regulations and guidelines.</li> <li>UNEP-GEF phase 1 commences.</li> <li>Commencement of early phases of sweet potato &amp; rinderpest vaccine trials through ABSP.</li> </ul>	<ul style="list-style-type: none"> <li>NCST</li> <li>Two donor organisations-DGIS &amp; USAID.</li> <li>NACBAA committee, KABP/BTA'</li> <li>Scientists (in KARI, Universities, regulatory and government providing both technical &amp; policy support).</li> </ul>	<ul style="list-style-type: none"> <li>Draft Regulations and Guidelines of 1998 and workshop proceedings organised by BTA/KABP.</li> <li>KARI-Institutional Biosafety Committee (IBC) formed.</li> <li>KEPHIS is established through a government Legal Notice.</li> <li>It has been argued that this phase was reactive and only strengthened the science aspect of the regulatory process (Sander, 2007).</li> </ul>
2 1998-2005	<ul style="list-style-type: none"> <li>Implementation of the 1998 approved regulations.</li> <li>Research trials under confinement commence.</li> <li>Early drafting of the biotechnology policy and the biosafety bill under phase 2 of UNEP-GEF programme and BIOERN programme.</li> <li>Building biosafety and biotechnology science capacity through BIO-EARN.</li> <li>Building regulatory capacity of NBC &amp; regulators by PBS.</li> </ul>	<ul style="list-style-type: none"> <li>Three main donors: UNEP-GEF, USAID through the PBS, SIDA funding the BIOERN programme.</li> <li>Scientists (practice and policy, as members of NBC or affiliated to donors and NGOs, in academic &amp; research institutions).</li> <li>Government through NCST &amp; regulatory agencies.</li> </ul>	<ul style="list-style-type: none"> <li>Establishment of the National Biosafety Framework (NBF) under UNEP-GEF phase 2 commences &amp; consequent Implementation.</li> <li>The NBC is established laying an institutional foundation for regulatory approval of GE trials.</li> <li>Approval of 1<sup>st</sup> GM trial-the sweet potato &amp; later importation of research materials from USA by KARI for field trials.</li> <li>Commencement of IRMA phase 1 project.</li> <li>Enactment of EMCA Act and creation of NEMA under provisions of this Act.</li> <li>Kenya signs &amp; ratifies the Cartagena Protocol and consequent efforts to operationalise it through review of first regulations leading to the revised version (RoK, 2003b).</li> <li>Contained laboratory &amp; greenhouse approval to conduct <i>Bt</i> maize trial using <i>Bt</i> leaves &amp; <i>Bt</i> seeds respectively.</li> <li><i>Bt</i> cotton approved for screen house trials.</li> <li>Transgenic cassava approved for screen house trials.</li> <li>Transgenic sweet potato failure to confer resistance to sweet potato feathery mottle virus becomes publicly known.</li> <li><i>Bt</i> maize &amp; <i>Bt</i> cotton approved for open field trials.</li> <li>Various capacity building efforts targeting policy makers, scientists, regulators, journalists and public through combined initiative of many stakeholders.</li> <li>Several policy instruments drafted (biotechnology policy; biosafety bill, implementation manuals and guidelines).</li> <li>Early stages of activism of actors.</li> </ul>
2005-	Increased debate on the biosafety	USAID through PBS.	Proliferation of NGOs (for/against GE technology and enactment of the biosafety bill) with

2009	<p>bill with bill becoming law.</p> <ul style="list-style-type: none"> <li>-Counter accusations and activities amongst opponents.</li> <li>-Drafting of regulations gains momentum under the financial support of PBS.</li> </ul>	<p>Industry partnering with other players in GE sensitisation.</p> <ul style="list-style-type: none"> <li>-Scientists (individuals and within groups) make a case for biotechnology and biosafety bill.</li> <li>-NBC though NCST.</li> <li>-Journalists targeted for training and publicity.</li> <li>-Many media agencies reporting on biotechnology and biosafety bill.</li> </ul>	<p>intensified lobbying by these groups (see Appendices 5 &amp; 9).</p> <ul style="list-style-type: none"> <li>-Planting of <i>Bt</i> maize open field trial. The trial is publicly halted (Daily Nation, 2005) &amp; consequent re-approval with reviewed and stricter biosafety requirements.</li> <li>-Importation of <i>Bt</i> cotton seeds and planting of <i>Bt</i> cotton open field trials.</li> <li>-Open field trial cassava application denied approval by NBC.</li> <li>-Adoption of biotechnology policy and biosafety bill in 2006.</li> <li>-<i>Bt</i> cotton open field trial used by proponents of GMOs and scientists to lobby for political support (The People Daily, 2007).</li> <li>-Approval of second <i>Bt</i> cotton trial.</li> <li>-First &amp; second mentioning of the biosafety bill in parliament.</li> <li>-Continued sensitization of policy makers on GMOs activities in Kenya and abroad.</li> <li>-Parliament prologues to pave way for general elections.</li> <li>-The civil society supported by some members of parliament publishes the biotechnology and biosafety bill (2008) &amp; comparative analysis of both the civil society preferred bill and the government fronted bill.</li> <li>-1<sup>st</sup> attempt to have draft biosafety bill 2008 published, later approved by parliament and president in Dec. 2008 and Feb. 2009 respectively.</li> <li>-Science (through scientific community) integrates with politics through politicians and policy makers.</li> </ul>
4	<p>Post-Biosafety Act 2009 &amp; beyond</p>	<p>(Hypothetical)</p> <p>Consumers, farmers, regulators at various institutions (e.g. KEPHIS, NEMA, KEBS, Public Health) and government through the NBA.</p>	<p>More tensions are envisaged based on the challenges of implementation (see Chapter five).</p> <ul style="list-style-type: none"> <li>-Possible counter activities from the civil society organisations based on GE performance.</li> <li>-Government likely to take up a proactive role unlike the first 3 phases in the management of controversies.</li> </ul>

Source: Various secondary sources and interview data. See abbreviations on pages ix-x.

## Appendix 7: Major developments surrounding the formulation of the biosafety bill 2008

Period	Activity
<i>The signing and ratification of Cartagena Protocol in 2000 and 2002 set various activities into motion.</i>	
Jul 2002	Scientists and lawyers developed zero draft copies of the biotechnology policy and the biosafety bill after a two weeks meeting.
Mar 2003	1 <sup>st</sup> discussion of the zero drafts of the biotechnology policy and biosafety bill by scientists and lawyers in a two-days meeting.
Apr 2003	1 <sup>st</sup> stakeholders one week meeting to discuss the draft copies.
Aug 2003	Two-days meeting with members of parliament to discuss the draft copies.
Nov 2003	One-week stakeholders meeting comprising of policy makers with majority being members of parliament to sensitise them on biosafety bill.
May 2004	A two-day study tour for parliamentary committees members to biotechnology facilities in Kenya to assess the biotechnology and biosafety capacity as they debated the bill in parliament.
Mar 2005	One-week meeting of seventeen experts (scientists and lawyers) to review both the policy and the bill.
Apr 2006	Interested stakeholders discussed the revised draft policy documents to identify any omissions for further input.
July 2006	Final reviewed documents presented to the Attorney General by the minister for Science and Technology for perusal before being presented to the cabinet.
Sep 2006	The policy and the bill approved by the cabinet.
22 Jun 2007	The bill is published in the Kenya gazette to solicit public comments.
22 Jun-11 Jul 2007	The period it remained in the public domain, significant number of public comments received.
July 2007	A half-day stakeholders meeting to discuss the bill and be sensitization on its importance.
Aug 2007	One-week meeting by a committee of experts (three lawyers and five scientists) to review the comments from the public. The committee proposed a number of technically sound amendments to the bill.
Oct 2007	-The biosafety bill, 2007 tabled in 9 <sup>th</sup> Parliament by Minister for Education, Science and Technology. It went through the 1 <sup>st</sup> and 2 <sup>nd</sup> reading. -Parliament was dissolved before the 3 <sup>rd</sup> reading, hence further discussion ceased.
Feb 2008	NCST incorporated the proposed amendments to the biosafety bill, 2007 and consequently requested the Attorney General to re-publish the then biosafety bill, 2008.
27 Jun – 16 July 2008	Bill published in the Kenya gazette and put in public domain for comments. No public comments were raised.
July 2008	Biosafety bill, 2008 tabled in the 10 <sup>th</sup> parliament by the newly elected Minister for Higher, Education Science and Technology.
Nov 27 2008	The bill passed the second reading and moved to the committee stage of the whole parliamentary house.
9 Dec 2008	The bill passed after it was approved by the parliament.
12 Feb 2009	Presidential assent and finally bill became law. It was officially published in a special issue of the Kenyan gazette in Feb. 2009 as Biosafety Act 2009.

Source: Primary and secondary sources [(Macharia, 2008; various documents detailed in Appendix 9; PBS resource materials ([www.pbs.org](http://www.pbs.org)) & interviews]

## Appendix 8: Analysis of NBC members (between 1998-2008)

<b>Institution</b> (For abbreviations, see pages ix-x and Tables 2 & 3).	<b>Traynor &amp; Macharia, 2003</b>	<b>Minutes of NBC</b>	<b>Proposed NBA</b>
NCST	√	√	√
KEPHIS	√	√	√
ILRI	√	√	-
Ministry of Agriculture (MOA)	√	√	√
UON, Dept of Biological Sciences	√	√	x
KENFAP/KNFU	√	√	x
ABSF	√	√	x
KIPI	√	√	x
KEMRI	√	√	x
MOPH&S (previously Ministry of Health)	√	√	√
CIN	√	√	x
STAK	√	√	x
MOHE,S&T	√	√	√
KEBS	√	√	√
NEMA	√	√	√
Plant Breeders Association of Kenya/PBK	x	√	x
Department of Veterinary Services/DVS	x	√	√
Kenya Wildlife Services/KWS	√	x	x
Biotechnology Trust Africa	√	x	x
Kenyatta University	√	x	x
Ministry of Trade & Industry	√	x	x
AG's Chambers	x	x	x
Ministry of finance	-	-	√
PCPB	x	x	x

**Note:** The table shows who have since joined (√) or exited (x) based on the new proposed members of the NBA as per the Biosafety Act, 2009; compared with Traynor and Macharia (2003) and some minutes of a number of NBC meetings obtained for this study between 2007-2008. All the state institutions not listed under the new Act will cease to be members. Instead, representation will be based on expertise not confined to institutions as has been the case. The civil societies/public representation will be based on who the Minister appoints (clause 6k).

## Appendix 9: Media reports

Source and date	Activity/ Media report title	Summary of issue/s	Remark/Writer
Sunday Nation (SN), August 28, 2005.	"Government halts research on maize"	Open <i>Bt</i> Maize trial site at Kiboko erroneously sprayed with insecticide.	Article created tension between scientists and government
SN, 1 Jan, 2006.	"Permanent secretary sees no conflict in his role and directorship in GM food body"	Role of former KARI director (now the PS in ministry of agriculture) questioned as an advisor to a biotechnology programme. Public worried about conflict of interest.	The newspaper correspondent, opinion and analysis.
The People Daily, 9 Jan 2007	"Cotton research critical phase"	Meant to inform public about <i>Bt</i> cotton trials in Mwea, KARI.	H. Wahinya
Daily Nation (DN), 22 Oct 08	"Biosafety bill to regulate modern biotechnology activities"	NBC/NCST government statement countering anti-GMOs media reports regarding the biosafety bill 2008.	Statement endorsed by 19 NBC institutional members.
DN, 8th Dec 2008	"Intense lobbying of house set to debate GMOs"	Two camps openly support or oppose the biosafety bill.	Article written in relation to scientists' open support for biotechnology.
SN, 23rd Nov 2008	"Scientists endorse gene altered foods"		G. Gathura in the food production column
People Daily, 24 Nov 08	"University lecturers endorse GMO bill"		P. Mutuma in the national record column.
Sunday Times, 23 Nov 08	"Embrace biotechnology use, say dons, experts"		N. Chepkemoi
The East African, 26 May – 1 June, 2008.	"How Africa's media is pushing GM crops"	Article claims that pro-biotechnology reports have increased, fronted by scientific organisations and funded by biotechnology industry.	J. Mbaria, special correspondent in the Focus column.
SN, March 23, 2008	"Farmers planting maize that poses threat to humans"		J. Mbaria
Science Africa magazine on Science, Innovation & Development (SAM on SID) Nov 6-Dec 6, 08 issue.	"Enact biosafety bill 2008 now"	An exclusive interview with a former member of parliament sensitized on <i>Bt</i> cotton locally and abroad.	C. Osodo
	"Biosafety: former MP's first hand experience"		
	"This time MPs must enact Kenya's Biosafety Bill 2008"	The editor beseeches the MPs in the 10 <sup>th</sup> parliament to enact the bill 2008.	Editorial
	"Opposition to biosafety bill misleading"	-	D. Wafula & D. Orunge
	"Biotechnology offers opportunities to tackle food insecurity"	Article talks about the biotechnology potential and the need for a biosafety law to regulate it.	F. Nang'ayo
	"Scientists root for greater maize yields to tackle food"	Articles records two scientists' views regarding the <i>Bt</i> Maize	N. Mwaura

	insecurity in Kenya"	IRMA project and its potential to address food insecurity.	
(SAM on SID magazine, 15 Sep- 15 Oct 08 issue.	"African scientists' time to wake up"	Article writes on African scientists and implies that they are not doing enough to solve problems facing Africa today.	
DN, 8th Dec 2008	Draft code of practice for handling GMOs (foods).	KEBS, a government regulator prepares to adopt GMOs food.	Remark by KEBS director
25 Sep 2008	Government launches BioWARE. Hon. W. Ruto, Minister for agriculture as the guest of honour and flanked by senior officers from the Ministry of HES & T.	Minister for agriculture publicly supports biotechnology & biosafety bill. He emphasises that as a scientist, he understands biotechnology science.	The speeches recorded and transcribed.
22 Sep 2008	1 <sup>st</sup> All Africa congress on biotechnology in Nairobi, Kenya, officially opened by an Assistant minister, Ministry of Agriculture.	The assistant minister in his off speech remarks vowed to support the biosafety bill in parliament together with other ministers.	
	1st all Africa congress on biotechnology in Nairobi, Kenya. The forum officially closed by Dr. K. Mweria, Assistant minister, MOHES&T.	Key note speech by Prof. S. Abdulrazak, NCST chief executive, and he appeals for support to have the bill enacted.	
SN, 7 Dec 2008	"To our Kenyan MPs. The biosafety bill 2008 before parliament. What is wrong with the biosafety bill 2008"	The assistant minister in his off-speech remarks said that the ministry was keen in providing a regulatory framework for biotechnology deployment.	
	Press statement by National Council of Churches of Kenya (NCCCK).	Open letter to MPs by civil society citing anomalies in the bill 2008, claiming that it seeks to sell public to multinationals.	Article appears in the Africa News column.
		NCCCK issues a press statement on matters of national concern one of which is the GMOs. It claims that government is in a hurry to adopt GMOs without giving the public freedom to decide for or against them.	Statement prepared by the executive committee in 3-4 Dec 2008 & endorsed by Rev. Dr. C. Kibicho (Chairman) and Rev. Canon P. Karanja (General Secretary).
AG-chambers, 10 June 2008	Parallel bill "the biotechnology and biosafety bill, 2008" and accompanying comparative analytical report of both the government and civil society bills.	The civil society under the KBioC.	The bill proposed in parliament by Hon. S. Ruteere, an opponent of GMOs.
DN, 25 Nov 08	"Biosafety bill 2008. Kenyan MPs selling the country?"	Civil society under KBioC publishes weaknesses perceived to be inherent in the bill and proposes a way forward to address the weaknesses.	Article endorsed by 66 members of the complainant umbrella body- KBioC.
DN, 23 Dec 08	"Farmers' union asks President Kibaki not to sign the biosafety bill 2008"	Farmers organised by KBioC, a consortium of over 60 farmers organisations protest in the streets in Nairobi demanding that the president desist from signing the controversial biosafety bill which had just been approved by parliament.	K. Kibiwott in the National News column.

**Source:** Records of workshops; various secondary media sources on biosafety bill, government related developments showing its support for the regulatory process and biotechnology & other public concerns.